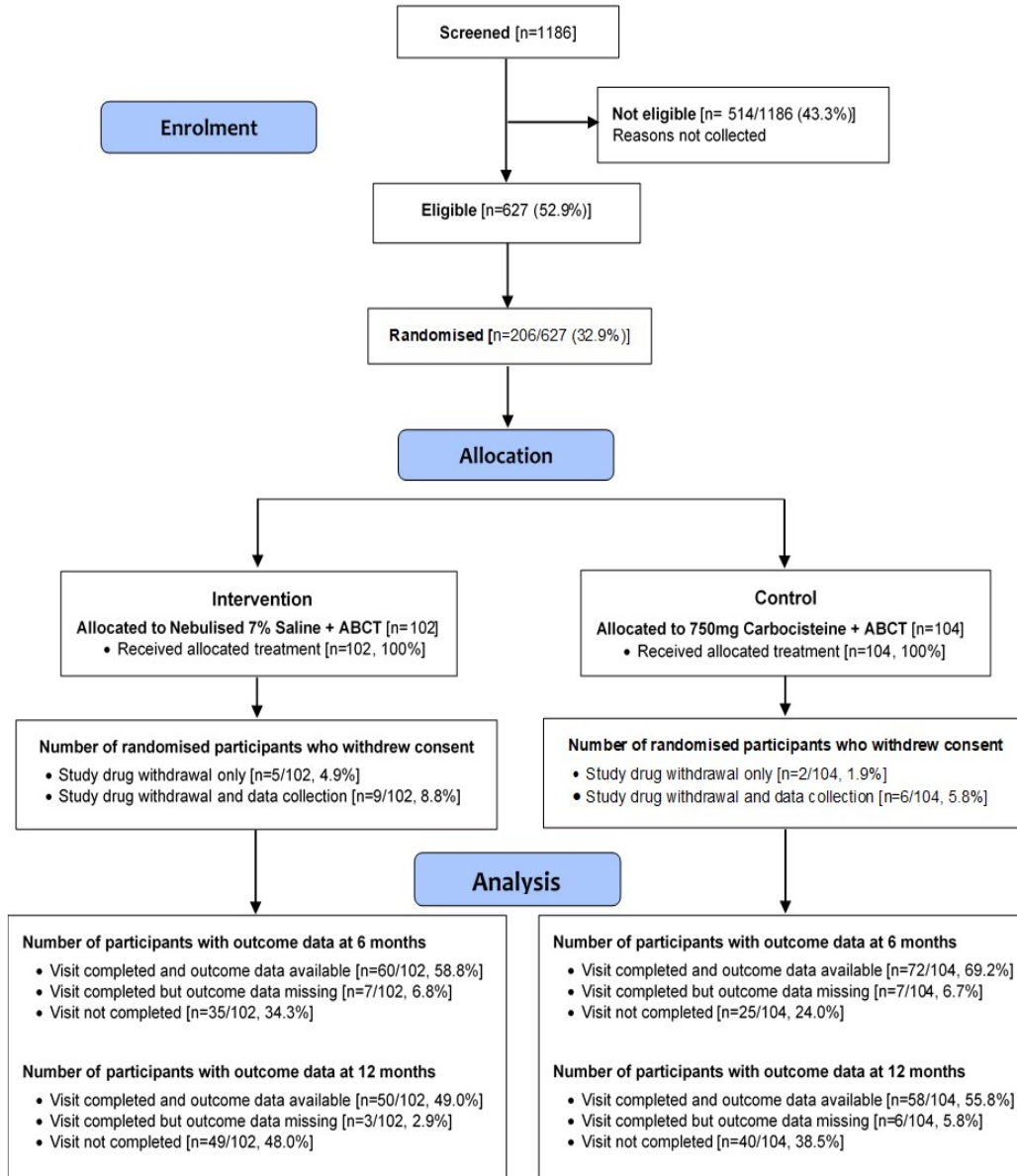


Flow diagram



Baseline characteristics

Baseline demographics

		Treatment		
Baseline Characteristics		Control	Intervention	Total
Age in years	N	104.0	102.0	206.0
	Mean	66.6	67.1	66.8
	Std Dev	9.7	9.3	9.5
	Minimum	39.0	48.0	39.0
	Lower Quartile	60.0	60.0	60.0
	Median	67.0	67.0	67.0
	Upper Quartile	74.5	75.0	75.0
	Maximum	84.0	86.0	86.0
Age	18-64	43 (41%)	43 (42%)	86 (42%)
	65-84	61 (59%)	56 (55%)	117 (57%)
	≥ 85	0 (0%)	3 (3%)	3 (1%)
Sex at birth	Male	52 (50%)	58 (57%)	110 (53%)
	Female	52 (50%)	44 (43%)	96 (47%)
Height (cm)	N	101	101	202
	Mean	167.6	168.4	168.0
	Std Dev	11.4	9.7	10.6
	Minimum	121.0	150.4	121.0
	Lower Quartile	160.0	161.0	161.0
	Median	166.0	168.0	167.9
	Upper Quartile	176.0	176.0	176.0
	Maximum	190.5	192.0	192.0
Weight (kg)	N	101	101	202
	Mean	81.6	76.8	79.2
	Std Dev	21.7	19.8	20.8
	Minimum	38.7	43.2	38.7
	Lower Quartile	65.7	60.0	62.0
	Median	79.0	75.0	76.0
	Upper Quartile	98.8	90.3	93.5
	Maximum	173.5	152.1	173.5
BMI	N	101	101	202
	Mean	28.9	27.1	28.0
	Std Dev	6.5	6.9	6.8

		Treatment		
Baseline Characteristics		Control	Intervention	Total
	Minimum	17.0	13.9	13.9
	Lower Quartile	24.3	22.5	23.5
	Median	28.8	25.3	27.1
	Upper Quartile	32.3	30.4	31.6
	Maximum	64.1	65.8	65.8
GOLD Classification	Class I	16 (15%)	16 (16%)	32 (16%)
	Class II	47 (45%)	46 (45%)	93 (45%)
	Class III	27 (26%)	24 (24%)	51 (25%)
	Class IV	14 (13%)	16 (16%)	30 (15%)

Baseline characteristics

Baseline measurements of outcomes

			Treatment		
Baseline measurements of outcome			Control (N=104)	Intervention (N=102)	Total
CAT score		N	100	97	197
		Mean	24.0	23.7	23.8
		Std Dev	7.3	7.5	7.4
		Minimum	6.0	9.0	6.0
		Lower Quartile	19.5	18.0	19.0
		Median	24.5	24.0	24.0
		Upper Quartile	29.5	29.0	29.0
		Maximum	37.0	39.0	39.0
LCQ	Physical score	N	101	97	198
		Mean	4.2	4.2	4.2
		Std Dev	1.2	1.2	1.2
		Minimum	1.4	1.8	1.4
		Lower Quartile	3.4	3.3	3.3
		Median	4.0	4.3	4.2
		Upper Quartile	5.1	5.1	5.1
		Maximum	6.6	6.5	6.6
	Psychological score	N	101	97	198
		Mean	4.3	4.6	4.5
		Std Dev	1.6	1.5	1.5
		Minimum	1.3	1.1	1.1
		Lower Quartile	3.0	3.6	3.3
		Median	4.3	4.9	4.6
		Upper Quartile	5.6	5.9	5.7
		Maximum	7.0	7.0	7.0
	Social score	N	100	97	197
		Mean	4.4	4.6	4.5
		Std Dev	1.6	1.4	1.5
		Minimum	1.0	1.0	1.0
		Lower Quartile	3.5	3.5	3.5
		Median	4.5	4.8	4.5
		Upper Quartile	5.5	5.8	5.8
		Maximum	7.0	7.0	7.0
	Total score	N	100	97	197
		Mean	13.0	13.5	13.2
		Std Dev	4.0	3.9	4.0
		Minimum	4.6	3.9	3.9
		Lower Quartile	9.9	10.7	10.3
		Median	13.0	13.1	13.1

Baseline measurements of outcome			Treatment		
			Control (N=104)	Intervention (N=102)	Total
		Upper Quartile	16.1	16.6	16.2
		Maximum	20.6	20.5	20.6
SGRQ	Activity score	N	102	97	199
		Mean	71.2	71.7	71.5
		Std Dev	23.6	21.4	22.5
		Minimum	6.0	6.2	6.0
		Lower Quartile	55.0	59.5	59.5
		Median	77.7	73.0	73.7
		Upper Quartile	92.5	92.5	92.5
		Maximum	100.0	100.0	100.0
	Impacts score	N	102	97	199
		Mean	44.1	46.1	45.1
		Std Dev	20.4	22.5	21.5
		Minimum	0.0	0.0	0.0
		Lower Quartile	28.7	31.3	29.9
		Median	43.9	47.1	44.9
		Upper Quartile	57.9	60.8	58.6
		Maximum	92.9	96.8	96.8
	Symptoms score	N	102	97	199
		Mean	69.8	72.9	71.3
		Std Dev	17.4	16.6	17.0
		Minimum	31.4	25.5	25.5
		Lower Quartile	58.2	62.7	60.4
		Median	72.1	74.9	73.1
		Upper Quartile	84.3	84.4	84.4
		Maximum	97.5	100.0	100.0
	Total score	N	102	97	199
		Mean	56.6	58.3	57.4
		Std Dev	19.0	19.1	19.0
		Minimum	11.0	7.5	7.5
		Lower Quartile	41.4	43.0	41.7
		Median	60.5	61.7	61.4
		Upper Quartile	69.6	72.0	71.3
		Maximum	92.6	91.8	92.6
FEV1	% of predicted	N	104	102	206
		Mean	57.4	54.7	56.1
		Std Dev	23.4	21.7	22.6
		Minimum	14.9	6.3	6.3
		Lower Quartile	39.9	38.8	39.0
		Median	56.2	54.0	55.5
		Upper Quartile	72.9	70.7	71.2

			Treatment		
Baseline measurements of outcome			Control (N=104)	Intervention (N=102)	Total
	Actual (L)	Maximum	130.2	104.0	130.2
		N	104	102	206
		Mean	1.5	1.5	1.5
		Std Dev	0.8	0.7	0.7
		Minimum	0.4	0.4	0.4
		Lower Quartile	0.9	1.0	1.0
		Median	1.4	1.4	1.4
		Upper Quartile	1.9	1.9	1.9
	Predicted (L)	Maximum	4.3	3.3	4.3
		N	103	98	201
		Mean	2.7	2.7	2.7
		Std Dev	0.7	0.6	0.6
		Minimum	1.3	1.6	1.3
		Lower Quartile	2.1	2.4	2.3
		Median	2.6	2.7	2.7
		Upper Quartile	3.1	3.1	3.1
		Maximum	4.4	4.6	4.6
FEV6	% of predicted	N	100	98	198
		Mean	69.3	68.8	69.0
		Std Dev	19.2	19.7	19.4
		Minimum	29.8	11.1	11.1
		Lower Quartile	56.9	56.8	56.8
		Median	69.2	69.6	69.5
		Upper Quartile	82.7	82.5	82.5
		Maximum	131.4	118.2	131.4
	Actual (L)	N	102	102	204
		Mean	2.4	2.5	2.4
		Std Dev	0.9	0.9	0.9
		Minimum	0.5	0.4	0.4
		Lower Quartile	1.7	1.8	1.8
		Median	2.3	2.4	2.3
		Upper Quartile	2.9	3.0	3.0
		Maximum	5.7	4.9	5.7
	Predicted (L)	N	100	98	198
		Mean	3.5	3.6	3.5
		Std Dev	0.9	0.8	0.8
		Minimum	1.6	2.1	1.6
		Lower Quartile	2.8	3.0	2.9
		Median	3.4	3.5	3.5
		Upper Quartile	4.1	4.1	4.1
		Maximum	5.7	5.9	5.9

			Treatment		
Baseline measurements of outcome			Control (N=104)	Intervention (N=102)	Total
Ratio FEV1:FEV6	% of predicted	N	100	98	198
		Mean	0.8	0.8	0.8
		Std Dev	0.2	0.3	0.3
		Minimum	0.4	0.1	0.1
		Lower Quartile	0.7	0.6	0.6
		Median	0.8	0.8	0.8
		Upper Quartile	0.9	0.9	0.9
		Maximum	1.1	2.9	2.9
	Actual (L)	N	102	102	204
		Mean	0.6	0.6	0.6
		Std Dev	0.2	0.2	0.2
		Minimum	0.3	0.2	0.2
		Lower Quartile	0.5	0.5	0.5
		Median	0.6	0.6	0.6
		Upper Quartile	0.7	0.7	0.7
		Maximum	2.5	2.1	2.5
	Predicted (L)	N	100	98	198
		Mean	0.8	0.8	0.8
		Std Dev	0.1	0.0	0.0
		Minimum	0.5	0.7	0.5
		Lower Quartile	0.8	0.8	0.8
		Median	0.8	0.8	0.8
		Upper Quartile	0.8	0.8	0.8
		Maximum	1.3	0.9	1.3

Outcome measures - Primary outcome analysis

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
CAT score	Baseline	Intervention	97	23.66	7.53	9	18	24	29	39
		Control	100	24.02	7.30	6	19.5	24.5	29.5	37
	12 months	Intervention	50	21.72	8.40	6	16	21.5	29	36
		Control	58	20.17	8.77	2	13	19.5	27	36
	Change*	Intervention	50	-1.60	6.05	-14	-6	-1	3	13
		Control	56	-3.30	7.18	-24	-7.5	-2.5	1.5	10

* Change from baseline to 12 months (i.e. 12 months - baseline).

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	56		.
	Intervention	50	1.48 (-0.97, 3.94)	0.232
Unadjusted*	Control	56		.
	Intervention	50	1.66 (-0.83, 4.15)	0.189

*adjusting for baseline CAT score only.

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	2.97 (-0.95, 6.89)	0.135
	Nebulised 7% Saline + ABCT (Intervention)	1.41 (-1.83, 4.65)	0.373
	CAT Total Score (Baseline)	0.67 (0.52, 0.83)	0.000
	Smoking Status (Current smoker)	2.60 (-0.26, 5.45)	0.073
	GOLD (3 and 4)	1.62 (-0.59, 3.82)	0.149

Key secondary outcome measure 1 - Health related quality of life

1.1 CAT score at baseline and 6 months

CAT scores at baseline, 6 months and change from baseline to 6 months

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
CAT score	Baseline	Intervention	97	23.66	7.53	9	18	24	29	39
		Control	100	24.02	7.30	6	19.5	24.5	29.5	37
	6 months	Intervention	60	22.66	8.28	7	15	23.5	28.5	37
		Control	72	21.36	9.00	4	14.5	21	28.5	40
	Change*	Intervention	60	-0.49	6.17	-16	-4	0	2.5	17
		Control	70	-2.59	6.41	-19	-6	-2	2	11

Linear regression to compare 6 month CAT scores between treatment groups

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	750 mg Carbocisteine + ABCT (Control)	70		.
	Nebulised 7% Saline + ABCT (Intervention)	60	1.898 (-0.27, 4.07)	0.086
Unadjusted*	750 mg Carbocisteine + ABCT (Control)	70		.
	Nebulised 7% Saline + ABCT (Intervention)	60	1.939 (-0.22, 4.09)	0.078

*adjusting for baseline CAT score only.

Linear regression to compare 6 month CAT scores using multiple imputation

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	1.30 (-2.22, 4.81)	0.467
	Nebulised 7% Saline + ABCT (Intervention)	2.08 (0.10, 4.06)	0.040
	CAT Total Score (Baseline)	0.82 (0.67, 0.97)	0.000
	Smoking Status (Current smoker)	0.87 (-1.06, 2.80)	0.376
	GOLD (3 and 4)	-0.08 (-2.25, 2.09)	0.940

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

LCQ at baseline, 6 months and change from baseline to 6 months

		Domain	Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
LCQ scores	Baseline	Physical	Intervention	97	4.19	1.21	1.75	3.25	4.25	5.13	6.50
			Control	101	4.23	1.19	1.38	3.38	4.00	5.13	6.63
		Psychology	Intervention	97	4.63	1.50	1.14	3.57	4.86	5.86	7.00
			Control	101	4.33	1.56	1.29	3.00	4.29	5.57	7.00
		Social	Intervention	97	4.64	1.44	1.00	3.50	4.75	5.75	7.00
			Control	100	4.45	1.59	1.00	3.50	4.50	5.50	7.00
		Total	Intervention	97	13.46	3.87	3.89	10.66	13.05	16.64	20.50
			Control	100	13.03	4.04	4.57	9.89	13.04	16.13	20.63
	6 months	Physical	Intervention	60	4.53	1.15	1.75	3.81	4.44	5.38	6.63
			Control	71	4.55	1.38	1.38	3.38	4.63	5.50	7.00
		Psychology	Intervention	60	5.19	1.40	1.86	4.07	5.36	6.43	7.00
			Control	71	4.86	1.80	1.00	3.43	5.43	6.43	7.00
		Social	Intervention	60	5.13	1.40	2.00	4.25	5.13	6.38	7.00
			Control	70	5.10	1.60	1.50	4.00	5.38	6.25	7.00
		Total	Intervention	60	14.84	3.72	5.61	12.34	14.79	18.29	20.63
			Control	69	14.57	4.41	5.09	11.32	15.36	18.05	21.00
	Change*	Total score	Intervention	60	1.32	2.91	-5.14	-0.27	1.15	3.08	7.79
			Control	68	1.71	3.02	-3.50	-0.39	1.46	3.63	13.05

Linear regression to compare 6 month LCQ scores between treatment groups

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	68		.
	Intervention	60	-0.203 (-1.21, 0.81)	0.691
Unadjusted*	Control	68		.
	Intervention	60	-0.244 (-1.25, 0.76)	0.632

*adjusting for baseline total LCQ score only.

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

Linear regression of 6 month LCQ scores using multiple imputation

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	5.54 (3.69, 7.39)	0.000
	Nebulised 7% Saline + ABCT (Intervention)	-0.31 (-1.24, 0.63)	0.516
	LCQ (Baseline)	0.74 (0.63, 0.86)	0.000
	Smoking Status (Current smoker)	-0.58 (-1.66, 0.51)	0.289
	GOLD (3 and 4)	-0.61 (-1.56, 0.34)	0.204

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

LCQ at baseline, 12 months and change from baseline to 12 months

		Domain	Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
LCQ scores	Baseline	Physical	Intervention	97	4.19	1.21	1.75	3.25	4.25	5.13	6.50
			Control	101	4.23	1.19	1.38	3.38	4.00	5.13	6.63
		Psychology	Intervention	97	4.63	1.50	1.14	3.57	4.86	5.86	7.00
			Control	101	4.33	1.56	1.29	3.00	4.29	5.57	7.00
		Social	Intervention	97	4.64	1.44	1.00	3.50	4.75	5.75	7.00
			Control	100	4.45	1.59	1.00	3.50	4.50	5.50	7.00
		Total	Intervention	97	13.46	3.87	3.89	10.66	13.05	16.64	20.50
			Control	100	13.03	4.04	4.57	9.89	13.04	16.13	20.63
	12 months	Physical	Intervention	49	4.49	1.25	2.25	3.50	4.38	5.63	6.50
			Control	58	4.86	1.28	2.00	4.13	5.06	5.75	7.00
		Psychology	Intervention	49	4.99	1.71	1.29	3.86	5.29	6.43	7.00
			Control	58	5.18	1.60	1.71	4.29	5.43	6.83	7.00
		Social	Intervention	49	4.83	1.66	1.50	3.50	5.00	6.50	7.00
			Control	57	5.26	1.48	1.50	4.25	5.75	6.50	7.00
		Total	Intervention	49	14.30	4.36	5.79	11.36	15.13	17.66	20.50
			Control	57	15.40	4.04	6.29	12.61	16.07	18.83	20.75
	Change*	Total score	Intervention	49	0.64	3.48	-7.43	-1.70	0.86	2.57	7.64
			Control	56	2.27	3.27	-2.89	-0.14	1.77	3.45	12.80

* Change from baseline to 12 months (i.e. 12 months - baseline).

Linear regression to compare 12 month LCQ scores between treatment groups

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	56		.
	Intervention	49	-1.465 (-2.72, -0.21)	0.023
Unadjusted*	Control	56		.
	Intervention	49	-1.452 (-2.70, -0.21)	0.023

*adjusting for baseline total LCQ score only.

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

Linear regression of 12 month LCQ scores using multiple imputation

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	6.17 (3.60, 8.73)	0.000
	Nebulised 7% Saline + ABCT (Intervention)	-1.37 (-2.82, 0.08)	0.063
	LCQ (Baseline)	0.73 (0.55, 0.91)	0.000
	Smoking Status (Current smoker)	0.06 (-1.55, 1.67)	0.941
	GOLD (3 and 4)	-0.99 (-2.50, 0.51)	0.188

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

SGRQ at baseline, 6 months and change from baseline to 6 months

		Domain	Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
SGRQ scores	Baseline	Activity	Intervention	97	71.71	21.38	6.21	59.46	73.04	92.51	100.00
			Control	102	71.24	23.62	5.96	55.03	77.75	92.51	100.00
		Impacts	Intervention	97	46.14	22.54	0.00	31.31	47.11	60.80	96.81
			Control	102	44.09	20.44	0.00	28.69	43.86	57.88	92.87
		Symptom	Intervention	97	72.90	16.56	25.45	62.70	74.91	84.42	100.00
			Control	102	69.82	17.36	31.35	58.21	72.11	84.26	97.48
		Total	Intervention	97	58.33	19.08	7.53	43.03	61.68	72.05	91.75
			Control	102	56.57	18.97	11.01	41.38	60.52	69.56	92.65
	6 months	Activity	Intervention	60	70.27	23.78	10.47	58.82	73.00	92.51	100.00
			Control	72	70.05	24.81	5.96	53.62	79.03	88.61	100.00
		Impacts	Intervention	60	39.89	21.73	3.89	22.68	35.57	57.21	87.29
			Control	72	41.77	21.51	4.35	22.96	40.26	60.34	85.54
		Symptom	Intervention	60	63.01	18.66	21.37	50.43	61.31	79.51	93.58
			Control	72	60.05	22.42	0.00	45.42	60.42	78.62	100.00
		Total	Intervention	60	52.89	19.53	11.85	39.43	52.30	66.41	88.96
			Control	72	53.37	19.80	11.56	39.78	53.76	71.26	89.23
	Change*	Total score	Intervention	60	-4.10	9.19	-31.57	-10.70	-1.78	2.24	12.41
			Control	72	-4.06	10.40	-34.47	-9.15	-3.33	3.49	21.60

*Change from baseline total score to 6 months total score (i.e. 6 months - baseline).

Linear regression to compare 6 month SGRQ total scores between treatment groups

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	72		.
	Intervention	60	-0.216 (-3.58, 3.15)	0.899
Unadjusted	Control	72		.
	Intervention	60	-0.065 (-3.47, 3.34)	0.970

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

Linear regression of 6 month SGRQ total scores using multiple imputation

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	-0.53 (-7.34, 6.29)	0.876
	Nebulised 7% Saline + ABCT (Intervention)	-0.23 (-3.63, 3.18)	0.894
	SGRQ (Baseline)	0.91 (0.80, 1.03)	0.000
	Smoking Status (Current smoker)	1.05 (-2.33, 4.43)	0.540
	GOLD (3 and 4)	4.34 (0.66, 8.02)	0.022

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

SGRQ at baseline, 12 months and change from baseline to 12 months

		Domain	Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
SGRQ scores	Baseline	Activity	Intervention	97	71.71	21.38	6.21	59.46	73.04	92.51	100.00
			Control	102	71.24	23.62	5.96	55.03	77.75	92.51	100.00
		Impacts	Intervention	97	46.14	22.54	0.00	31.31	47.11	60.80	96.81
			Control	102	44.09	20.44	0.00	28.69	43.86	57.88	92.87
		Symptom	Intervention	97	72.90	16.56	25.45	62.70	74.91	84.42	100.00
			Control	102	69.82	17.36	31.35	58.21	72.11	84.26	97.48
		Total	Intervention	97	58.33	19.08	7.53	43.03	61.68	72.05	91.75
			Control	102	56.57	18.97	11.01	41.38	60.52	69.56	92.65
	12 months	Activity	Intervention	49	70.01	27.32	0.00	59.46	79.74	92.51	100.00
			Control	58	68.54	23.65	6.29	54.20	72.29	92.51	100.00
		Impacts	Intervention	49	41.80	21.92	0.00	22.69	42.22	55.68	86.11
			Control	58	37.80	20.97	0.00	22.92	36.00	50.21	88.34
		Symptom	Intervention	49	63.50	21.35	18.28	50.59	65.24	81.93	95.20
			Control	58	62.88	20.58	16.41	47.75	65.38	79.38	95.20
		Total	Intervention	49	53.84	21.35	2.68	39.22	57.11	66.98	88.34
			Control	58	51.28	19.23	8.44	39.40	50.77	65.85	88.66
	Change*	Total score	Intervention	49	-3.15	14.31	-35.72	-10.13	-4.24	5.41	43.61
			Control	58	-5.19	13.11	-52.76	-10.09	-4.82	4.98	16.43

*Change from baseline total score to 12 months total score (i.e. 12 months - baseline).

Linear regression to compare 12 month SGRQ total scores between treatment groups

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	58		.
	Intervention	49	2.008 (-3.12, 7.13)	0.439
Unadjusted	Control	58		.
	Intervention	49	2.133 (-3.02, 7.28)	0.413

Key secondary outcome measure 1 - Health related quality of life

1.2 Quality of life assessment using the LCQ and SGRQ at 6 months and 1 year

Linear regression of 12 month SGRQ total scores using multiple imputation

	Parameter	Mean difference (95% CI)	Pr > t
Imputed adjusted model	Intercept	2.76 (-6.38, 11.90)	0.544
	Nebulised 7% Saline + ABCT (Intervention)	1.24 (-3.72, 6.20)	0.618
	SGRQ (Baseline)	0.81 (0.65, 0.98)	0.000
	Smoking Status (Current smoker)	2.43 (-4.50, 9.36)	0.473
	GOLD (3 and 4)	5.15 (-0.40, 10.69)	0.068

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.1 Number of exacerbations over a one year period requiring antibiotic therapy and/or systemic steroid treatment measured using exacerbation diaries when exacerbation is reported by the patient

Number of exacerbations over 12 months

		Treatment				
Demographic data		Control	Intervention	Total	Chi-square test for trend	p-value
Exacerbations group	0	58 (56%)	71 (70%)	129 (63%)	.	2.391 0.017
	1	21 (20%)	16 (16%)	37 (18%)	.	.
	2	11 (11%)	11 (11%)	22 (11%)	.	.
	3 or more	14 (13%)	4 (4%)	18 (9%)	.	.

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.2 Time to first exacerbation requiring antibiotic therapy and/or systemic steroids over one year measured using exacerbation diaries when exacerbation is reported by the participant

Summary of time to first exacerbation in days

Censored	Randomisation Result	N	Mean	Std Dev	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
Censor	Intervention	71	226.8	143.4	0.0	77.0	294.0	365.0	366.0
	Control	58	226.1	145.7	5.0	79.0	265.0	366.0	366.0
	Total	129	226.5	143.9	0.0	79.0	267.0	365.0	366.0
1st exacerbation	Intervention	31	132.8	101.2	12.0	42.0	104.0	252.0	296.0
	Control	46	128.1	92.2	3.0	50.0	113.5	195.0	315.0
	Total	77	130.0	95.3	3.0	44.0	107.0	210.0	315.0

Time to first exacerbation in days - adjusted

Exacerbation over 12 months					Adjusted Cox proportional hazards model					
		Censored (%)	Event (%)	Total	B	SE	p-value	Hazard ratio (exp[B])	Lower 95% Confidence Limit for HR	Upper 95% Confidence Limit for HR
Randomisation group	750 mg Carbocisteine + ABCT (Control)	58 (45%)	46 (60%)	77 (37%)	0.000	.	.	1.000	.	.
	Nebulised 7% Saline + ABCT (Intervention	71 (55%)	31 (40%)	129 (63%)	-0.465	0.231	0.044	0.628	0.399	0.988
Smoking status	Never smoked and ex-smoker	68 (53%)	52 (68%)	120 (58%)	0.000	.	.	1.000	.	.
	Current smoker	61 (47%)	25 (32%)	86 (42%)	-0.349	0.259	0.177	0.705	0.425	1.171
GOLD	GOLD 1 and 2	82 (64%)	43 (56%)	125 (61%)	0.000	.	.	1.000	.	.
	GOLD 3 and 4	47 (36%)	34 (44%)	81 (39%)	0.445	0.238	0.062	1.560	0.978	2.488

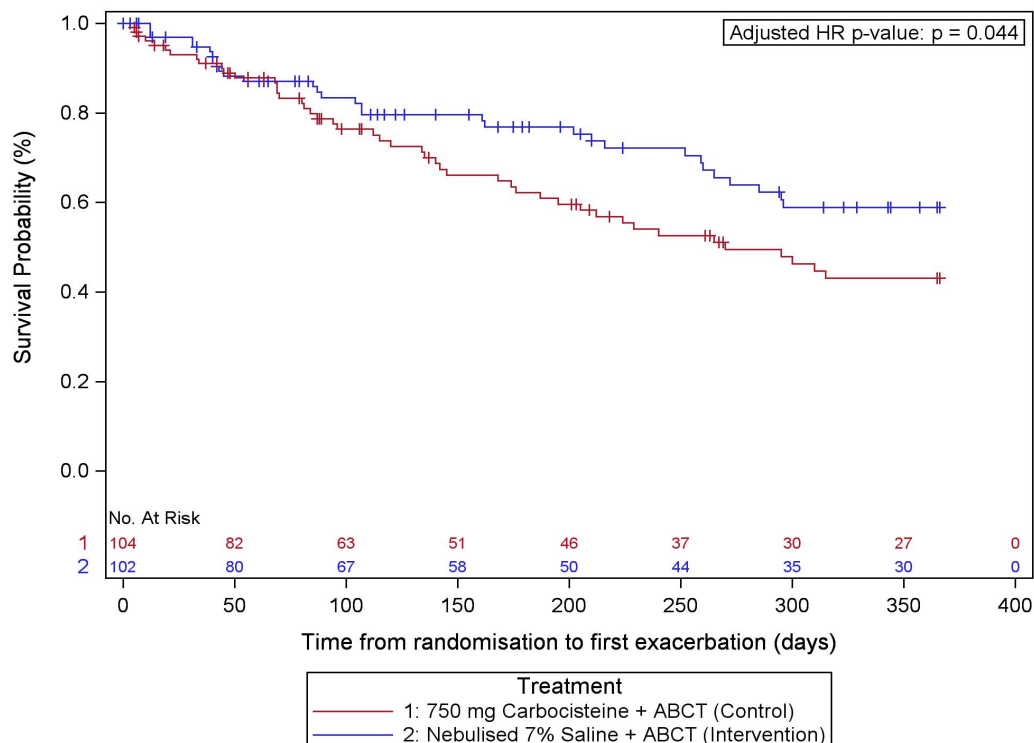
Time to first exacerbation in days - unadjusted

		Exacerbation over 12 months			Unadjusted Cox proportional hazards model					
		Censored (%)	Event (%)	Total	B	SE	p-value	Hazard ratio (exp[B])	Lower 95% Confidence Limit for HR	Upper 95% Confidence Limit for HR
Randomisation group	750 mg Carbocisteine + ABCT (Control)	58 (45%)	46 (60%)	77 (37%)	0.000	.	.	1.000	.	.
	Nebulised 7% Saline + ABCT (Intervention)	71 (55%)	31 (40%)	129 (63%)	-0.448	0.231	0.053	0.639	0.406	1.005

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.2 Time to first exacerbation requiring antibiotic therapy and/or systemic steroids over one year measured using exacerbation diaries when exacerbation is reported by the participant (continued)

Kaplan-Meier: Time to first exacerbation requiring antibiotic therapy and/or systemic steroids over 12 months



Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.3 Proportion of exacerbations needing antibiotic therapy over one year measured using exacerbation diaries when exacerbation is reported by the patient and concomitant medication recording

Number of exacerbations over 12 months

Exacerbations within 12 months of randomisation	Treatment		
	Control	Intervention	Total
No exacerbations	57 (55%)	70 (69%)	127 (62%)
≥1 exacerbations	47 (45%)	32 (31%)	79 (38%)

Number of exacerbations over 12 months requiring antibiotic therapy

Proportion of exacerbations needing antibiotic therapy over 12 months	Treatment		
	Control	Intervention	Total
0.00	4 (9%)	1 (3%)	5 (6%)
0.33	0 (0%)	1 (3%)	1 (1%)
0.50	5 (11%)	2 (6%)	7 (9%)
0.67	3 (6%)	0 (0%)	3 (4%)
0.80	2 (4%)	0 (0%)	2 (3%)
1.00	33 (70%)	28 (88%)	61 (77%)

Comparison of proportions of exacerbations requiring antibiotic therapy

	Percent with significant reduction	Lower 95% CI	Upper 95% CI	p-value
750 mg Carbocisteine + ABCT (Control)	80.85	69.60	92.10	.
Nebulised 7% Saline + ABCT (Intervention)	87.50	76.04	98.96	.
Difference*	-6.65	-22.71	9.41	0.434

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.4 Number of upper respiratory tract infections (URTI) over a one year period) assessed using the Wisconsin Upper Respiratory Symptom Survey-24 (WURSS-24)

Number of participants with at least one URTI

Number of participants with at least 1 URTI assessed using WURSS24	Treatment		
	Control	Intervention	Total
No URTI	75 (72%)	85 (83%)	160 (78%)
≥1 URTI	29 (28%)	17 (17%)	46 (22%)

Number of URTIs per participant

Number of URTIs per participant	Treatment		
	Control	Intervention	Total
1	15 (52%)	9 (53%)	24 (52%)
2	5 (17%)	8 (47%)	13 (28%)
3	5 (17%)	0 (0%)	5 (11%)
4	1 (3%)	0 (0%)	1 (2%)
5	3 (10%)	0 (0%)	3 (7%)

Number of URTIs per participant: grouped

Number of URTIs per participant	Treatment		
	Control	Intervention	Total
1	15 (52%)	9 (53%)	24 (52%)
>1	14 (48%)	8 (47%)	22 (48%)

Comparison of proportions of number of URTIs per treatment group

	Percent with significant reduction	Lower 95% CI	Upper 95% CI	p-value
750 mg Carbocisteine + ABCT (Control)	48.28	30.09	66.46	.
Nebulised 7% Saline + ABCT (Intervention)	47.06	23.33	70.79	.
Difference*	1.22	-28.68	31.11	0.936

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.5 Overall and COPD related hospital attendances/admissions over one year measured using healthcare usage questionnaire at baseline, 6 months and 12 months

Number of participants with at least one instance of hospital attendance/admission over 12 months

		Treatment		
		Control	Intervention	Total
Participants with at least one hospital attendance/admission over 12 months*	0	80 (77%)	83 (81%)	163 (79%)
	≥1	24 (23%)	19 (19%)	43 (21%)

Number of instances of reported hospital attendances/admissions

		Treatment		
		Control	Intervention	Total
Number of instances of reported attendances/admissions	1	23 (96%)	15 (79%)	38 (88%)
	2	1 (4%)	4 (21%)	5 (12%)

Number of participants with at least one COPD related instance of hospital attendance/admission over 12 months

		Treatment		
		Control	Intervention	Total
COPD related hospital attendance/admissions over 12 months*	No	17 (68%)	12 (52%)	29 (60%)
	Yes	8 (32%)	11 (48%)	19 (40%)

Number of COPD related hospital attendance/admissions over 12 months

		Treatment		
		Control	Intervention	Total
Number of COPD related hospital attendance/admissions over 12 months*	1	6 (86%)	8 (80%)	14 (82%)
	3	0 (0%)	1 (10%)	1 (6%)
	4	1 (14%)	1 (10%)	2 (12%)

Key secondary outcome measure 2 - Exacerbations and time to first exacerbation

2.6 Use of nebulised 7% sodium chloride in exacerbations measured using participant reported daily diaries

There were no cases of nebulised 7% sodium chloride being used in exacerbations, however there was one participant who was given `Sodium chloride 0.9%` for an exacerbation.

Key secondary outcome measure 3 - Potential pathogen microorganisms and viruses from sputum samples and combined nose and throat swabs

3.1 Proportion being infected with a potential pathogenic organism and viruses at 6 months and one year (from sputum samples and combined nose and throat swabs (if taken as part of standard care))

Line listing of viral lab results

Randomisation Result	Event Name		Has the participant had a recent nose and or throat swab for viral analysis?	If yes, how many were completed?	Lab result 1	Lab result 2	Lab result 3	Confirmation that Investigator has reviewed results
Control	Baseline (Post-Randomisation)	1556-21	Yes	2	Positive	Positive	.	Yes
		1645-2	Yes	2	Negative	Positive	.	Yes
		1884-4	Yes	1	Negative	.	.	Yes
		2178-2	Yes	2	Negative	Negative	.	Yes
		2909-4	Yes	1	Negative	.	.	Yes
		2972-1	Yes	3	Positive	Positive	Negative	Yes
	Week 8	1648-13	Yes	1	.	.	.	No
		1648-17	Yes	3	Negative	Negative	Negative	No
		2178-2	Yes	1	Negative	.	.	Yes
		2909-4	Yes	2	Negative	Negative	.	Yes
	Week 24 (Month 6)	1557-6	Yes	1	Negative	.	.	Yes
		1648-6	Yes	1	Negative	.	.	Yes
	Week 32	1641-1	Yes	3	Positive	Negative	Negative	No
		2176-4	Yes	1	Positive	.	.	No
	Week 16	1648-13	Yes	1	Negative	.	.	No
		2178-2	Yes	1	Negative	.	.	Yes
	Week 40	2176-4	Yes	1	Negative	.	.	No
Intervention	Baseline (Post-Randomisation)	1645-1	Yes	1	Negative	.	.	Yes
		1645-3	Yes	1	Negative	.	.	Yes
		2178-3	Yes	1	Negative	.	.	Yes
		2178-4	Yes	1	Negative	.	.	Yes
	Week 8	1556-7	Yes	1	Negative	.	.	Yes
		1556-8	Yes	1	Negative	.	.	Yes
		1557-1	Yes	1	Negative	.	.	Yes
		1648-15	Yes	2	Negative	Negative	.	Yes
	Week 48	1648-24	Yes	1	Negative	.	.	Yes
		1648-44	Yes	1	Negative	.	.	No
		1556-7	Yes	1	Positive	.	.	Yes
		1648-24	Yes	3	Negative	.	Negative	No
	Week 24 (Month 6)	2176-5	Yes	2	Negative	Negative	.	Yes
		1648-36	Yes	1	Negative	.	.	Yes
		1648-5	Yes	1	Negative	.	.	Yes
		1648-42	Yes	1	Negative	.	.	Yes
	Week 32	1648-5	Yes	1	Negative	.	.	No
		1648-42	Yes	2	Negative	Negative	.	No
	Week 16	1648-42	Yes	2	Negative	Negative	.	No

Randomisation Result	Event Name		Has the participant had a recent nose and or throat swab for viral analysis?	If yes, how many were completed?	Lab result 1	Lab result 2	Lab result 3	Confirmation that Investigator has reviewed results
	Week 40	1648-35	Yes	2	Negative	Negative	.	No

Key secondary outcome measure 4 - Viral transmissibility (household contacts to participant and participant to household)

Number of participants who had information regarding viral transmissibility

Number of participants who have completed a viral transmissibility form	Treatment		
	Control	Intervention	Total
No completed	104 (100%)	27 (26%)	131 (64%)
Completed	0 (0%)	75 (74%)	75 (36%)

Viral transmissibility summary

Viral transmissible data		Treatment		
		Control	Intervention	Total
Total number of recorded viruses	N	.	45 (100%)	45 (100%)
Number of participants with at least one virus	At least one virus	.	35 (100%)	35 (100%)
Total number of transmissible viruses per participant	1	.	26 (74%)	26 (74%)
	2	.	8 (23%)	8 (23%)
	3	.	1 (3%)	1 (3%)
Number of viruses linked to an exacerbation	No	.	32 (71%)	32 (71%)
	Yes	.	13 (29%)	13 (29%)

Key secondary outcome measure 5 - Lung function

5.1 Forced Expired Volume in 1 second (FEV1), forced vital capacity (FVC) and mid-expiratory flows at 6 months and one year (FEV6 is used as the surrogate of FVC)

FEV1 Actual: 6 months

Increase or decrease in Actual FEV1 between baseline and 6 months

FEV1 Actual		Treatment		
		Control	Intervention	Total
Number of participants with an increase or decrease between baseline and 6 months*	Missing	43 (.%)	50 (.%)	93 (.%)
	Decrease	29 (48%)	28 (54%)	57 (50%)
	Increase	29 (48%)	22 (42%)	51 (45%)
	No change	3 (5%)	2 (4%)	5 (4%)

Summary of FEV1 Actual values at baseline and 6 months

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
FEV1 Actual	Baseline	Intervention	102	1.51	0.67	0.41	1.00	1.43	1.89	3.26
		Control	104	1.54	0.77	0.42	0.93	1.36	1.92	4.27
	6 months	Intervention	52	1.43	0.57	0.45	0.97	1.39	1.72	2.98
		Control	61	1.53	0.84	0.47	0.94	1.38	1.91	4.42
	Change*	Intervention	52	-0.04	0.24	-0.85	-0.16	-0.03	0.07	0.63
		Control	61	-0.00	0.23	-0.58	-0.12	0.00	0.09	1.15

Linear regression for change in FEV1 actual (adjusted and unadjusted): 6 months

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	61		.
	Intervention	52	-0.03 (-0.12, 0.06)	0.514
Unadjusted*	Control	61		.
	Intervention	52	-0.03 (-0.12, 0.05)	0.441

Key secondary outcome measure 5 - Lung function

5.1 Forced Expired Volume in 1 second (FEV1), forced vital capacity (FVC) and mid-expiratory flows at 6 months and one year (FEV6 is used as the surrogate of FVC)

FEV1 Actual: 12 months

Increase or decrease in Actual FEV1 between baseline and 12 months

FEV1 Actual		Treatment		
		Control	Intervention	Total
Number of participants with an increase or decrease between baseline and 12 months*	Missing	54 (.%)	57 (.%)	111 (.%)
	Decrease	30 (60%)	24 (53%)	54 (57%)
	Increase	19 (38%)	21 (47%)	40 (42%)
	No change	1 (2%)	0 (0%)	1 (1%)

Summary of FEV1 Actual values at baseline and 12 months

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
FEV1 Actual	Baseline	Intervention	102	1.51	0.67	0.41	1.00	1.43	1.89	3.26
		Control	104	1.54	0.77	0.42	0.93	1.36	1.92	4.27
	12 months	Intervention	45	1.45	0.58	0.54	1.02	1.54	1.73	3.10
		Control	50	1.49	0.76	0.55	0.91	1.33	1.82	4.21
	Change*	Intervention	45	-0.05	0.25	-0.71	-0.18	-0.02	0.08	0.77
		Control	50	-0.04	0.19	-0.37	-0.16	-0.05	0.08	0.37

Linear regression for change in FEV1 actual (adjusted and unadjusted): 12 months

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	50		.
	Intervention	45	-0.01 (-0.10, 0.08)	0.860
Unadjusted*	Control	50		.
	Intervention	45	-0.01 (-0.10, 0.08)	0.788

Key secondary outcome measure 5 - Lung function

5.1 Forced Expired Volume in 1 second (FEV1), forced vital capacity (FVC) and mid-expiratory flows at 6 months and one year (FEV6 is used as the surrogate of FVC)

FEV6 Actual: 6 months

Increase or decrease in FEV6 Actual between baseline and 6 months

FEV6 Actual		Treatment		
		Control	Intervention	Total
Number of participants with an increase or decrease between baseline and 6 months*	Missing	46 (.%)	51 (.%)	97 (.%)
	Decrease	34 (59%)	27 (53%)	61 (56%)
	Increase	24 (41%)	21 (41%)	45 (41%)
	No change	0 (0%)	3 (6%)	3 (3%)

Summary of FEV6 Actual values at baseline and 6 months

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
FEV6 Actual	Baseline	Intervention	102	2.47	0.92	0.42	1.82	2.40	3.03	4.92
		Control	102	2.36	0.92	0.48	1.73	2.29	2.85	5.70
	6 months	Intervention	51	2.32	0.75	0.47	1.92	2.18	2.70	4.45
		Control	60	2.36	0.99	0.41	1.64	2.23	2.90	5.83
	Change*	Intervention	51	-0.11	0.61	-2.05	-0.35	-0.02	0.16	1.50
		Control	58	-0.05	0.47	-1.31	-0.22	-0.10	0.15	2.34

Linear regression for change in FEV6 Actual (adjusted and unadjusted): 6 months

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	58		.
	Intervention	51	-0.05 (-0.25, 0.15)	0.619
Unadjusted*	Control	58		.
	Intervention	51	-0.05 (-0.24, 0.15)	0.631

Key secondary outcome measure 5 - Lung function

5.1 Forced Expired Volume in 1 second (FEV1), forced vital capacity (FVC) and mid-expiratory flows at 6 months and one year (FEV6 is used as the surrogate of FVC)

FEV6 Actual: 12 months

Increase or decrease in FEV6 Actual between baseline and 12 months

FEV6 Actual	Treatment		
	Control	Intervention	Total
Number of participants with an increase or decrease between baseline and 12 months*	Missing	55 (.%)	58 (.%)
	Decrease	31 (63%)	27 (61%)
	Increase	18 (37%)	17 (39%)

Summary of FEV6 Actual values at baseline and 12 months

		Randomisation Result	N	Mean	Std.Dev	Min	Q1	Median	Q3	Max
FEV6 Actual	Baseline	Nebulised 7% Saline + ABCT (Intervention)	102	2.47	0.92	0.42	1.82	2.40	3.03	4.92
		750 mg Carbocisteine + ABCT (Control)	102	2.36	0.92	0.48	1.73	2.29	2.85	5.70
	12 months	Nebulised 7% Saline + ABCT (Intervention)	44	2.36	0.73	1.27	1.88	2.20	2.73	4.91
		750 mg Carbocisteine + ABCT (Control)	50	2.36	0.97	0.47	1.64	2.18	2.92	5.64
	Change*	Nebulised 7% Saline + ABCT (Intervention)	44	-0.07	0.49	-1.41	-0.34	-0.14	0.14	1.63
		750 mg Carbocisteine + ABCT (Control)	49	-0.00	0.56	-1.27	-0.27	-0.06	0.17	2.43

Linear regression for change in FEV6 Actual (adjusted and unadjusted): 12 months

Analysis			Mean difference (95% CI)	Pr > t
Adjusted	Control	49		.
	Intervention	44	-0.08 (-0.28, 0.11)	0.409
Unadjusted*	Control	49		.
	Intervention	44	-0.05 (-0.25, 0.15)	0.603

Key secondary outcome measure 6 - Health economic benefits

Not provided in this statistical analysis summary.

Key secondary outcome measure 7 - Adverse effects over one year measured using participant reported daily diaries

Summary of adverse events

Adverse Event data		Treatment		
		Control	Intervention	Total
Total number of adverse events*	N	137 (100%)	152 (100%)	289 (100%)
Number of participants with at least one AE	None	25 (32%)	21 (28%)	46 (30%)
	At least one AE	52 (68%)	54 (72%)	106 (70%)
Total number of adverse events per participant	0	52 (50%)	48 (47%)	100 (49%)
	1	19 (18%)	25 (25%)	44 (21%)
	2	13 (13%)	6 (6%)	19 (9%)
	3	6 (6%)	6 (6%)	12 (6%)
	4	9 (9%)	9 (9%)	18 (9%)
	5	2 (2%)	1 (1%)	3 (1%)
	6	1 (1%)	3 (3%)	4 (2%)
	7	0 (0%)	1 (1%)	1 (0%)
	8	1 (1%)	2 (2%)	3 (1%)
	14	1 (1%)	0 (0%)	1 (0%)
	15	0 (0%)	1 (1%)	1 (0%)
Causality summary	Unavailable	0 (.%)	2 (.%)	2 (.%)
	Unrelated	114 (86%)	103 (70%)	217 (78%)
	Possibly related	18 (14%)	45 (30%)	63 (23%)
Severity summary	Unknown	2 (.%)	1 (.%)	1 (.%)
	Unavailable	1 (.%)	0 (.%)	3 (.%)
	Mild	91 (70%)	109 (73%)	200 (72%)
	Moderate	36 (28%)	36 (24%)	72 (26%)
	Severe	3 (2%)	4 (3%)	7 (3%)

* Participants can have more than one AE recorded.

Key secondary outcome measure 7 - Adverse effects over one year measured using participant reported daily diaries

Summary of serious adverse events

		Treatment		
Serious Adverse Event data		Control	Intervention	Total
Total number of Serious Adverse Events*	N	13 (10%)	10 (7%)	23 (8%)
Number of participants with at least one SAE	At least one SAE	5 (10%)	6 (11%)	11 (11%)
Total number of SAEs per participant	1	5 (5%)	7 (7%)	12 (6%)
	2	2 (2%)	0 (0%)	2 (1%)
	3	0 (0%)	1 (1%)	1 (0%)
	4	1 (1%)	0 (0%)	1 (0%)

* Participants can have more than one SAE recorded.

Key secondary outcome measure 8 - Adherence with interventions assessed by weekly participant charts and enquired at study appointments over one year

Missed doses: number of participants with missed doses

			Treatment		
			Control	Intervention	Total
Number of participants with missed doses	Week 8	Unknown	7 (.%)	11 (.%)	18 (.%)
		No	44 (54%)	23 (30%)	67 (8%)
		Yes	38 (46%)	54 (70%)	92 (12%)
	Week 16	Unknown	9 (.%)	8 (.%)	17 (.%)
		No	48 (73%)	36 (55%)	84 (11%)
		Yes	18 (27%)	29 (45%)	47 (6%)
	Week 24 (Month 6)	Unknown	16 (.%)	10 (.%)	26 (.%)
		No	44 (70%)	24 (42%)	68 (9%)
		Yes	19 (30%)	33 (58%)	52 (7%)
	Week 32	Unknown	11 (.%)	9 (.%)	20 (.%)
		No	47 (87%)	27 (55%)	74 (9%)
		Yes	7 (13%)	22 (45%)	29 (4%)
	Week 40	Unknown	13 (.%)	10 (.%)	23 (.%)
		No	43 (83%)	25 (57%)	68 (9%)
		Yes	9 (17%)	19 (43%)	28 (4%)
	Week 48	Unknown	9 (.%)	15 (.%)	24 (.%)
		No	49 (89%)	21 (54%)	70 (9%)
		Yes	6 (11%)	18 (46%)	24 (3%)
	Week 52 (Month 12)	Unknown	12 (.%)	8 (.%)	20 (.%)
		No	43 (83%)	23 (51%)	66 (8%)
		Yes	9 (17%)	22 (49%)	31 (4%)

Key secondary outcome measure 8 - Adherence with interventions assessed by weekly participant charts and enquired at study appointments over one year

Number of doses missed: for those who said they had missed a dose

			Treatment		
			Control	Intervention	Total
Number of doses missed at each timepoint	Week 8	Unknown	2 (.%)	3 (.%)	5 (.%)
		One	6 (17%)	7 (14%)	13 (5%)
		Two	1 (3%)	8 (16%)	9 (3%)
		Three	6 (17%)	5 (10%)	11 (4%)
		Four	1 (3%)	5 (10%)	6 (2%)
		Five or more	22 (61%)	26 (51%)	48 (17%)
	Week 16	Unknown	0 (.%)	1 (.%)	1 (.%)
		One	2 (11%)	1 (4%)	3 (1%)
		Two	1 (6%)	4 (14%)	5 (2%)
		Three	2 (11%)	3 (11%)	5 (2%)
		Four	3 (17%)	2 (7%)	5 (2%)
		Five or more	10 (56%)	18 (64%)	28 (10%)
	Week 24 (Month 6)	Unknown	0 (.%)	2 (.%)	2 (.%)
		One	4 (21%)	3 (10%)	7 (2%)
		Two	4 (21%)	2 (6%)	6 (2%)
		Three	1 (5%)	3 (10%)	4 (1%)
		Four	0 (0%)	1 (3%)	1 (0%)
		Five or more	10 (53%)	22 (71%)	32 (11%)
	Week 32	Unknown	0 (.%)	3 (.%)	3 (.%)
		One	3 (43%)	1 (5%)	4 (1%)
		Two	0 (0%)	3 (16%)	3 (1%)
		Three	1 (14%)	0 (0%)	1 (0%)
		Four	0 (0%)	1 (5%)	1 (0%)
		Five or more	3 (43%)	14 (74%)	17 (6%)
	Week 40	Unknown	2 (.%)	1 (.%)	3 (.%)
		One	0 (0%)	2 (11%)	2 (1%)
		Two	2 (29%)	2 (11%)	4 (1%)
		Three	0 (0%)	3 (17%)	3 (1%)
		Four	2 (29%)	3 (17%)	5 (2%)
		Five or more	3 (43%)	8 (44%)	11 (4%)
	Week 48	Unknown	1 (.%)	0 (.%)	1 (.%)
		One	4 (80%)	1 (6%)	5 (2%)
		Two	0 (0%)	1 (6%)	1 (0%)

			Treatment		
			Control	Intervention	Total
	Three		0 (0%)	1 (6%)	1 (0%)
	Four		0 (0%)	1 (6%)	1 (0%)
	Five or more		1 (20%)	14 (78%)	15 (5%)
Week 52 (Month 12)	Unknown		0 (.%)	2 (.%)	2 (.%)
	One		2 (22%)	2 (10%)	4 (1%)
	Two		1 (11%)	2 (10%)	3 (1%)
	Three		0 (0%)	0 (0%)	0 (0%)
	Four		1 (11%)	1 (5%)	2 (1%)
	Five or more		5 (56%)	15 (75%)	20 (7%)

Adverse events

Line listing of adverse events

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
1	Intervention	1556-32	Edinburgh (Site 1)		.	.	.	.	.	.	.	.	.	.	.	.	Complete
2	Intervention	1646-3	Birmingham Heartlands (Site 12)		.	.	.	.	.	.	.	.	.	.	.	.	Complete
3	Intervention	1556-57	Edinburgh (Site 1)	community Aquired Pneumonia	13NOV2023	Yes	Moderate	Unrelated	.	17NOV2023	RF	Resolved	19NOV2023	AC	11	27.1	Complete
4	Intervention	1556-63	Edinburgh (Site 1)	Acute Abdominal pain with vomitting and rectal bleeding	30NOV2023	Yes	Moderate	Unrelated	.	12DEC2023	RF	Resolved	18DEC2023	JC	7	27.1	Complete
5	Intervention	1556-63	Edinburgh (Site 1)	Acute flare up of diverticulitis	01FEB2024	Yes	Moderate	Unrelated	.	07FEB2024	AH	Resolved	02FEB2024	JC	11	27.1	Complete
6	Intervention	1556-63	Edinburgh (Site 1)	Flare of diverticulitis	17FEB2024	Yes	Moderate	Unrelated	.	20FEB2024	AH	Resolved	19FEB2024	AC/SD	11	27.1	Complete
7	Intervention	1556-7	Edinburgh (Site 1)	Pneumonia and Flu A	05DEC2022	Yes	Moderate	Unrelated	N/A	07DEC2022	RF	Resolved	10DEC2022	SD	11	27.1	Complete
8	Intervention	1557-1	Glasgow (Site 2)	Pulmonary Embolism	23AUG2022	Yes	Moderate	Unrelated	N/A	01SEP2022	HB	Resolved	21AUG2023	C Dunne	23	27.1	Complete
9	Intervention	2177-4	Princess Royal (Site 16)	Emergency spinal/back surgery	01NOV2023	Yes	Moderate	Unrelated	.	07NOV2023	LL	Resolved	10NOV2023	Anna Posada	26	27.1	Complete
10	Intervention	3040-12	Aberdeen (site 25)	Acute gastroenteritis	10JUN2024	Yes	Moderate	Unrelated	.	18JUN2024	CKRW	Resolved	22JUL2024	AN	11	27.1	Complete
11	Intervention	1556-55	Edinburgh (Site 1)	Fractured neck of femur	24APR2024	Yes	Severe	Unrelated	.	01MAY2024	RF	Resolved	28MAY2024	JC	12	27.1	Complete
12	Intervention	1720-5	Hull (Site 15)	non-infective exacerbation of COPD	05APR2023	Yes	Severe	Unrelated	.	10APR2024	MC	Resolved	06APR2023	Rachel Floc	23	27.1	Complete
13	Intervention	1899-4	Bath (site 9)	Vit B12 deficiency	06SEP2023	No	.	Unrelated	.	10OCT2023	JS	Ongoing	.	Zandille ma	14	27.1	Complete
14	Intervention	2909-2	Walsall (Site 24)	Chest Infection	15DEC2023	No	Mild	.	.	20MAR2024	KI	Resolved	19DEC2023	R Chadwick	11	27.1	Incomplete
15	Intervention	2909-2	Walsall (Site 24)	Enlarged Prostate (Deteroration)	18MAR2024	No	Mild	.	.	20MAR2024	KI	Ongoing	.	R Chadwick	22	27.1	Incomplete
16	Intervention	1556-28	Edinburgh (Site 1)	Blocked sinuses	03MAR2023	No	Mild	Unrelated	N/A	22MAR2023	Dr Ruzanna	Ongoing	.	J,C	23	27.1	Complete
17	Intervention	1556-32	Edinburgh (Site 1)	Dizziness/ Lighheaded	17FEB2023	No	Mild	Unrelated	N/A	21FEB2023	RF	Resolved	28FEB2023	SD	17	27.1	Complete
18	Intervention	1556-32	Edinburgh (Site 1)	Cold symptoms	17FEB2023	No	Mild	Unrelated	N/A	21FEB2023	RF	Resolved	28FEB2023	SD	11	27.1	Complete

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
19	Intervention	1556-40	Edinburgh (Site 1)	Head wound and haematoma	25MAR2023	No	Mild	Unrelated	N/A	23MAY2023	RF	Resolved	25MAR2023	SD	12	27.1	Complete
20	Intervention	1556-40	Edinburgh (Site 1)	Dizziness	05JUL2023	No	Mild	Unrelated	.	06SEP2023	RF	Resolved	19JUL2023	JC	17	27.1	Complete
21	Intervention	1556-42	Edinburgh (Site 1)	Burning sensation in mouth	09APR2023	No	Mild	Unrelated	.	31JAN2024	RF	Resolved	09JUN2023	JC	7	27.1	Complete
22	Intervention	1556-42	Edinburgh (Site 1)	Haemorrhage in eye (seen at routine optician appointment)	12JUL2023	No	Mild	Unrelated	N/A	06SEP2023	R.F	Resolved	01DEC2023	JC	6	27.1	Complete
23	Intervention	1556-42	Edinburgh (Site 1)	High cholesterol	26JUL2023	No	Mild	Unrelated	.	06SEP2023	R,F	Resolved	01DEC2023	JC	13	27.1	Complete
24	Intervention	1556-8	Edinburgh (Site 1)	Urinary Tract Infection	16FEB2023	No	Mild	Unrelated	N/A	22FEB2023	RF	Resolved	18FEB2023	SD	11	27.1	Complete
25	Intervention	1556-8	Edinburgh (Site 1)	Covid-19 positive(LFT)	15NOV2022	No	Mild	Unrelated	.	24JAN2023	RF	Resolved	05DEC2022	SD	11	27.1	Complete
26	Intervention	1557-1	Glasgow (Site 2)	Headaches	17DEC2021	No	Mild	Unrelated	N/A	06JAN2022	HB	Resolved	20DEC2021	CDunne	17	27.1	Complete
27	Intervention	1557-1	Glasgow (Site 2)	Ache of upper back bottom of shoulder blades	27DEC2021	No	Mild	Unrelated	N/A	06JAN2022	HB	Resolved	04APR2022	CDunne	15	27.1	Complete
28	Intervention	1557-1	Glasgow (Site 2)	Tiredness	21FEB2022	No	Mild	Unrelated	N/A	19APR2022	H.B.	Resolved	24FEB2022	David Jenki	8	27.1	Complete
29	Intervention	1557-1	Glasgow (Site 2)	Discomfort in legs	15MAR2022	No	Mild	Unrelated	N/A	19APR2022	H.B.	Resolved	20MAR2022	David Jenki	15	27.1	Complete
30	Intervention	1557-1	Glasgow (Site 2)	Muscles feel weak/limp	15MAR2022	No	Mild	Unrelated	N/A	19APR2022	H.B.	Resolved	20MAR2022	David Jenki	15	27.1	Complete
31	Intervention	1557-1	Glasgow (Site 2)	Intermittent Tiredness	14MAR2022	No	Mild	Unrelated	N/A	10JUN2022	HB	Ongoing	.	CDunne	8	27.1	Complete
32	Intervention	1557-1	Glasgow (Site 2)	Intermittent Headaches	27DEC2021	No	Mild	Unrelated	N/A	10JUN2022	HB	Ongoing	.	CDunne	17	27.1	Complete
33	Intervention	1557-1	Glasgow (Site 2)	Common Cold	27MAY2022	No	Mild	Unrelated	N/A	10JUN2022	HB	Resolved	06JUN2022	CDunne	11	27.1	Complete
34	Intervention	1557-1	Glasgow (Site 2)	Intermittent Discomfort in legs	13JUN2022	No	Mild	Unrelated	N/A	29JUL2022	H Bayes	Ongoing	.	CDunne	15	27.1	Complete
35	Intervention	1557-1	Glasgow (Site 2)	Fever After Covid Vaccination	16NOV2022	No	Mild	Unrelated	N/A	21NOV2022	HB	Resolved	18NOV2022	Femke Steff	12	27.1	Complete
36	Intervention	1557-7	Glasgow (Site 2)	Gash to Leg	11OCT2022	No	Mild	Unrelated	N/A	14OCT2022	HB	Ongoing	.	CDunne	12	27.1	Complete
37	Intervention	1648-19	Exeter (Site 11)	Fall	28MAR2023	No	Mild	Unrelated	N/A	29MAR2023	AM	Resolved	01APR2023	Anne McGahe	12	27.1	Complete
38	Intervention	1648-31	Exeter (Site 11)	Tested Positive for COVID	27FEB2023	No	Mild	Unrelated	N/A	01FEB2025	MG	Resolved	06MAR2023	Anne McGahe	11	27.1	Complete
39	Intervention	1648-35	Exeter (Site 11)	Generally feeling unwell	25DEC2023	No	Mild	Unrelated	.	14FEB2024	CM	Ongoing	.	ME	8	27.1	Complete

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40	Intervention	1648-36	Exeter (Site 11)	Chest Infection	02FEB2024	No	Mild	Unrelated	.	05FEB2024	CM	Resolved	29FEB2024	ME	11	27.1	Complete
41	Intervention	1648-42	Exeter (Site 11)	Common cold	15MAY2024	No	Mild	Unrelated	.	29MAY2024	CM	Resolved	17MAY2024	ME	11	27.1	Complete
42	Intervention	1648-43	Exeter (Site 11)	Covid19	03APR2024	No	Mild	Unrelated	.	19JUN2024	CM	Resolved	13APR2024	ME	11	27.1	Complete
43	Intervention	1648-44	Exeter (Site 11)	dizzy	19JUL2023	No	Mild	Unrelated	.	01FEB2025	MG	Resolved	.	Ingrid Seat	17	27.1	Complete
44	Intervention	1648-5	Exeter (Site 11)	Dry/cracked Lips	19JUN2022	No	Mild	Unrelated	N/A	01FEB2025	MG	Resolved	20JUN2022	Anne McGahe	7	27.1	Complete
45	Intervention	1720-2	Hull (Site 15)	Chest Pain under right Axilla	15JUN2022	No	Mild	Unrelated	N/A	04JUL2022	MC	Resolved	20JUN2022	Natalie Car	8	27.1	Complete
46	Intervention	1720-4	Hull (Site 15)	chest pain	24JUN2022	No	Mild	Unrelated	N/A	30AUG2022	MC	Ongoing	.	Natalie Car	8	27.1	Complete
47	Intervention	1720-7	Hull (Site 15)	constipation	11JAN2023	No	Mild	Unrelated	N/A	01MAR2023	MC	Resolved	01FEB2023	Rachel Floc	7	27.1	Complete
48	Intervention	1720-7	Hull (Site 15)	muscle twitch	11JAN2023	No	Mild	Unrelated	N/A	01MAR2023	MC	Resolved	26APR2023	Rachel Floc	15	27.1	Complete
49	Intervention	1899-4	Bath (site 9)	Flue	26MAR2023	No	Mild	Unrelated	N/A	28MAR2023	J Suntharal	Resolved	01APR2023	Zandile Mas	11	27.1	Complete
50	Intervention	1899-4	Bath (site 9)	Allergic reaction unknown agent	24MAY2023	No	Mild	Unrelated	.	24MAY2023	ZM	Resolved	26MAY2023	ZM	10	27.1	Complete
51	Intervention	1997-1	Hairmyres (Site 17)	neck pain	27DEC2022	No	Mild	Unrelated	N/A	29DEC2022	PB	Resolved	29JAN2025	M McKernan	15	27.1	Complete
52	Intervention	1997-1	Hairmyres (Site 17)	dry mouth and throat	12JAN2023	No	Mild	Unrelated	N/A	08FEB2023	PB	Resolved	08FEB2023	M McKernan	7	27.1	Complete
53	Intervention	2176-1	Newcastle (Site 10)	High temperature	23AUG2023	No	Mild	Unrelated	.	06SEP2023	ADS	Resolved	04SEP2023	K McRoberts	8	27.1	Complete
54	Intervention	2176-1	Newcastle (Site 10)	Urinary tract infection	08SEP2023	No	Mild	Unrelated	.	31OCT2023	ADS	Resolved	22SEP2023	K McRoberts	11	27.1	Complete
55	Intervention	2176-1	Newcastle (Site 10)	Fall at home, bruised leg	.	No	Mild	Unrelated	.	05DEC2023	HU	Resolved	.	KM	12	27.1	Complete
56	Intervention	2176-10	Newcastle (Site 10)	Patient attended A+E with swollen feet. Discharged same day. Patient states	01JUN2023	No	Mild	Unrelated	.	20JUN2023	ADS	Ongoing	.	Kate McRobe	8	27.1	Complete
57	Intervention	2176-10	Newcastle (Site 10)	Patient attended A+E for bilateral rib pain for 2 weeks. Increased SOB. Pat	03JUL2023	No	Mild	Unrelated	.	02AUG2023	ADS	Resolved	13JUL2023	K McRoberts	23	27.1	Complete
58	Intervention	2176-10	Newcastle (Site 10)	Shoulder pain on codiene	13JUL2023	No	Mild	Unrelated	.	02AUG2023	ADS	Ongoing	.	K McRoberts	15	27.1	Complete
59	Intervention	2176-10	Newcastle (Site 10)	Frozen shoulder	.	No	Mild	Unrelated	.	19APR2024	HU	Ongoing	.	KM	15	27.1	Complete

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60	Intervention	2176-10	Newcastle (Site 10)	Diarrhoea and vomiting	08MAR2024	No	Mild	Unrelated	.	18MAR2024	HU	Resolved	09MAR2024	SS	11	27.1	Complete
61	Intervention	2176-5	Newcastle (Site 10)	Back pain from coughing	04JAN2024	No	Mild	Unrelated	.	08JAN2024	HU	Ongoing	.	KM	15	27.1	Complete
62	Intervention	2176-5	Newcastle (Site 10)	Low saturations	03JAN2024	No	Mild	Unrelated	.	08JAN2024	HU	Resolved	03JAN2024	KM	13	27.1	Complete
63	Intervention	2176-5	Newcastle (Site 10)	Tachycardia	03JAN2024	No	Mild	Unrelated	.	08JAN2024	HU	Resolved	03JAN2024	KM	2	27.1	Complete
64	Intervention	2176-7	Newcastle (Site 10)	Urinary retention	03JUL2023	No	Mild	Unrelated	.	11JUL2023	ADS	Ongoing	.	Gillian Cur	21	27.1	Complete
65	Intervention	2177-2	Princess Royal (Site 16)	leg ulcer	01JUL2023	No	Mild	Unrelated	.	05SEP2023	LL	Ongoing	.	N Griffiths	24	27.1	Complete
66	Intervention	2178-1	Fife (Site 18)	Un-even heart rate	22JUN2023	No	Mild	Unrelated	.	28JUL2023	SF	Resolved	22JUN2023	Julie Penma	13	27.1	Complete
67	Intervention	2178-1	Fife (Site 18)	Headaches (Intermittent)	18MAY2023	No	Mild	Unrelated	.	28JUL2023	SF	Resolved	13JUL2023	Julie Penma	17	27.1	Complete
68	Intervention	2178-1	Fife (Site 18)	Loss of appetite and taste	05OCT2023	No	Mild	Unrelated	.	01NOV2023	DD	Resolved	18OCT2023	Julie Penma	14	27.1	Complete
69	Intervention	2178-1	Fife (Site 18)	Diarrhoea	13OCT2023	No	Mild	Unrelated	.	01NOV2023	DD	Resolved	16OCT2023	Julie Penma	7	27.1	Complete
70	Intervention	2178-3	Fife (Site 18)	Urine Infection	16SEP2023	No	Mild	Unrelated	.	29SEP2023	DD	Resolved	05OCT2023	Julie Penma	11	27.1	Complete
71	Intervention	2178-3	Fife (Site 18)	Right foot/ankle pain	01OCT2023	No	Mild	Unrelated	.	25JAN2024	SF	Resolved	01MAY2024	Julie Penma	15	27.1	Complete
72	Intervention	2178-4	Fife (Site 18)	Increase urination	18NOV2023	No	Mild	Unrelated	.	26JAN2024	SF	Resolved	30DEC2023	Anne Marie	21	27.1	Complete
73	Intervention	2178-4	Fife (Site 18)	Extreme thirst	02DEC2023	No	Mild	Unrelated	.	26JAN2024	SF	Resolved	30DEC2023	Anne Marie	8	27.1	Complete
74	Intervention	2178-4	Fife (Site 18)	Hypertension	12AUG2024	No	Mild	Unrelated	.	21AUG2024	SF	Ongoing	.	Julie Penma	27	27.1	Complete
75	Intervention	2178-4	Fife (Site 18)	Irregular pulse	12AUG2024	No	Mild	Unrelated	.	21AUG2024	SF	Ongoing	.	Julie Penma	13	27.1	Complete
76	Intervention	2909-2	Walsall (Site 24)	Cold like Symptoms	20OCT2023	No	Mild	Unrelated	.	25OCT2023	KI	Resolved	24OCT2023	R Chadwick	11	27.1	Complete
77	Intervention	2909-2	Walsall (Site 24)	Chest Infection	27OCT2023	No	Mild	Unrelated	.	29NOV2023	KI	Resolved	10NOV2023	Rob Chadwic	11	27.1	Complete
78	Intervention	3040-3	Aberdeen (site 25)	Tiredness	04APR2023	No	Mild	Unrelated	.	09JUN2023	DM	Resolved	14JUN2023	VF	8	27.1	Complete
79	Intervention	3040-3	Aberdeen (site 25)	Light headedness/ feeling faint	10MAY2023	No	Mild	Unrelated	.	09JUN2023	DM	Resolved	24MAY2023	VF	17	27.1	Complete
80	Intervention	3040-3	Aberdeen (site 25)	Discomfort in legs	17MAY2023	No	Mild	Unrelated	.	09JUN2023	DM	Resolved	14JUN2023	VF	15	27.1	Complete
81	Intervention	3040-3	Aberdeen (site 25)	UTI	23JUL2023	No	Mild	Unrelated	.	04AUG2023	DM	Resolved	29JUL2023	SM	11	27.1	Complete
82	Intervention	3040-9	Aberdeen (site 25)	Cold Symptoms	12OCT2023	No	Mild	Unrelated	.	08NOV2023	CRWK	Resolved	19OCT2023	SM	11	27.1	Complete

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83	Intervention	3040-9	Aberdeen (site 25)	Muscles feel weak/limp	13DEC2023	No	Mild	Unrelated	.	11JAN2024	DM	Resolved	14DEC2023	Vicki Frase	15	27.1	Complete
84	Intervention	1556-10	Edinburgh (Site 1)	Burning sensation in nose (intermittent)	29JUN2022	No	Mild	Possibly related	Expected	27OCT2022	RF	Ongoing	.	SD	23	27.1	Incomplete
85	Intervention	1557-1	Glasgow (Site 2)	Tingling of top lip	22DEC2021	No	Mild	Possibly related	Unexpected	06JAN2022	HB	Resolved	29DEC2021	CDunne	7	27.1	Complete
86	Intervention	1557-1	Glasgow (Site 2)	Salty taste	17DEC2021	No	Mild	Possibly related	Expected	22FEB2022	H.B.	Ongoing	.	David Jenki	17	27.1	Complete
87	Intervention	1557-1	Glasgow (Site 2)	Discomfort in Legs	28MAR2022	No	Mild	Possibly related	Expected	10JUN2022	HB	Resolved	11APR2022	CDunne	15	27.1	Complete
88	Intervention	1557-1	Glasgow (Site 2)	Hoarse Voice	11APR2022	No	Mild	Possibly related	Expected	10JUN2022	HB	Resolved	18APR2022	CDunne	23	27.1	Complete
89	Intervention	1557-7	Glasgow (Site 2)	Reflux	22JUL2022	No	Mild	Possibly related	Expected	09AUG2022	H.B.	Ongoing	.	David Jenki	7	27.1	Complete
90	Intervention	1557-7	Glasgow (Site 2)	Leg Cramps Intermittent	.	No	Mild	Possibly related	Expected	27SEP2022	HB	Ongoing	.	SP	15	27.1	Complete
91	Intervention	1645-1	Birmingham Good Hope (Site 13)	Difficulty breathing	15JUN2022	No	Mild	Possibly related	Expected	02DEC2022	NS	Resolved	17OCT2022	AR	23	27.1	Complete
92	Intervention	1648-42	Exeter (Site 11)	Cough after trial medication	08JUN2023	No	Mild	Possibly related	Expected	14DEC2023	CM	Ongoing	.	ME	23	27.1	Complete
93	Intervention	1720-2	Hull (Site 15)	Burning and Irritation in mouth for 1 hour post nebulization	29MAR2022	No	Mild	Possibly related	Expected	04JUL2022	MC	Resolved	29MAR2022	Natalie Car	7	27.1	Complete
94	Intervention	1720-2	Hull (Site 15)	Burning and Irritation in mouth for 1 hour post nebulization	05APR2022	No	Mild	Possibly related	Expected	04JUL2022	MC	Resolved	05APR2022	Natalie Car	7	27.1	Complete
95	Intervention	1720-2	Hull (Site 15)	Burning and Irritation in mouth for 1 hour post nebulization	12APR2022	No	Mild	Possibly related	Expected	04JUL2022	MC	Resolved	12APR2022	Natalie Car	7	27.1	Complete
96	Intervention	1720-2	Hull (Site 15)	Burning and Irritation in mouth for 1 hour post nebulization	19APR2022	No	Mild	Possibly related	Expected	04JUL2022	MC	Resolved	19APR2022	Natalie Car	7	27.1	Complete
97	Intervention	1720-4	Hull (Site 15)	Salty taste in mouth	24JUN2022	No	Mild	Possibly related	Expected	30AUG2022	MC	Ongoing	.	Natalie Car	17	27.1	Complete
98	Intervention	1720-5	Hull (Site 15)	Salty Taste in mouth	01JUL2022	No	Mild	Possibly related	Expected	15SEP2022	MC	Resolved	07JUL2022	Natalie Car	17	27.1	Complete
99	Intervention	1720-5	Hull (Site 15)	Swelling in Left foot	19AUG2022	No	Mild	Possibly related	Expected	15SEP2022	MC	Resolved	21AUG2022	Natalie Car	8	27.1	Complete
100	Intervention	1720-7	Hull (Site 15)	Tiredness	03NOV2022	No	Mild	Possibly related	Expected	16JAN2023	MC	Resolved	05NOV2022	Rachel Floc	8	27.1	Complete

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101	Intervention	1899-4	Bath (site 9)	sore mouth	07DEC2022	No	Mild	Possibly related	Expected	21DEC2022	JS	Resolved	14DEC2022	Katie White	7	27.1	Complete
102	Intervention	2176-1	Newcastle (Site 10)	Abdominal bloating/ discomfort on bending forward - awaiting scan from GP	24MAY2023	No	Mild	Possibly related	Expected	06JUN2023	TDS	Ongoing	.	KM	7	27.1	Complete
103	Intervention	2176-5	Newcastle (Site 10)	intermittent sore throat	06FEB2023	No	Mild	Possibly related	N/A	20JUN2023	ADS	Resolved	20FEB2023	KM	23	27.1	Complete
104	Intervention	2178-1	Fife (Site 18)	Salty Taste	23MAR2023	No	Mild	Possibly related	Expected	06APR2023	DD	Ongoing	.	Julie Penma	17	27.1	Complete
105	Intervention	2178-1	Fife (Site 18)	Burning / irritation in mouth	23MAR2023	No	Mild	Possibly related	Expected	06APR2023	DD	Resolved	06APR2023	Julie Penma	7	27.1	Complete
106	Intervention	2178-1	Fife (Site 18)	Increase in urination	24MAR2023	No	Mild	Possibly related	Expected	20APR2023	SF	Ongoing	.	Julie Penma	21	27.1	Complete
107	Intervention	2178-1	Fife (Site 18)	Lightheaded / Feeling faint (intermittently)	18MAY2023	No	Mild	Possibly related	Expected	28JUL2023	SF	Resolved	07DEC2023	Julie Penma	17	27.1	Complete
108	Intervention	2178-3	Fife (Site 18)	Salty Taste	12JUN2023	No	Mild	Possibly related	Expected	30JUN2023	SF	Ongoing	.	Julie Penma	17	27.1	Complete
109	Intervention	2178-3	Fife (Site 18)	Burning / irritation in mouth	12JUN2023	No	Mild	Possibly related	Expected	30JUN2023	SF	Resolved	07OCT2023	Julie Penma	7	27.1	Complete
110	Intervention	2178-4	Fife (Site 18)	Salty taste	18NOV2023	No	Mild	Possibly related	Expected	26JAN2024	SF	Ongoing	.	Anne Marie	17	27.1	Complete
111	Intervention	2178-4	Fife (Site 18)	Runny Nose	24FEB2024	No	Mild	Possibly related	Unexpected	22MAR2024	SF	Resolved	08JUN2024	Julie Penma	23	27.1	Complete
112	Intervention	2909-2	Walsall (Site 24)	Face Irritation (Itchiness)	16OCT2023	No	Mild	Possibly related	Expected	25OCT2023	KI	Ongoing	.	R Chadwick	24	27.1	Complete
113	Intervention	2909-2	Walsall (Site 24)	Stinging Eyes	23OCT2023	No	Mild	Possibly related	Expected	25OCT2023	KI	Resolved	23OCT2023	R Chadwick	6	27.1	Complete
114	Intervention	2909-2	Walsall (Site 24)	Loss of Taste (10min Post Neb)	05OCT2023	No	Mild	Possibly related	Expected	25OCT2023	KI	Ongoing	.	R Chadwick	17	27.1	Complete
115	Intervention	3040-11	Aberdeen (site 25)	Salty Taste	13SEP2023	No	Mild	Possibly related	Expected	05DEC2023	DM	Resolved	10DEC2023	VF	17	27.1	Complete
116	Intervention	3040-11	Aberdeen (site 25)	Chest pain from doing breathing exercises	11OCT2023	No	Mild	Possibly related	Unexpected	05DEC2023	DM	Resolved	10DEC2023	VF	8	27.1	Complete
117	Intervention	3040-11	Aberdeen (site 25)	Light headed/ Feeling faint	11OCT2023	No	Mild	Possibly related	Unexpected	05DEC2023	DM	Resolved	10DEC2023	VF	17	27.1	Complete
118	Intervention	3040-11	Aberdeen (site 25)	Increase/ decrease in urination	25OCT2023	No	Mild	Possibly related	Unexpected	05DEC2023	DM	Resolved	26OCT2023	VF	21	27.1	Complete
119	Intervention	3040-3	Aberdeen (site 25)	Salty Taste	26APR2023	No	Mild	Possibly related	Expected	09JUN2023	DM	Resolved	14JUN2023	VF	17	27.1	Complete
120	Intervention	3040-3	Aberdeen (site 25)	Extreme Thirst	03MAY2023	No	Mild	Possibly related	Unexpected	09JUN2023	DM	Resolved	14JUN2023	VF	8	27.1	Complete

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121	Intervention	3040-3	Aberdeen (site 25)	Trouble breathing	10MAY2023	No	Mild	Possibly related	Unexpected	09JUN2023	DM	Resolved	16MAY2023	VF	23	27.1	Complete
122	Intervention	3040-9	Aberdeen (site 25)	Salty taste	22JUN2023	No	Mild	Possibly related	Expected	06SEP2023	CRWK	Resolved	01JAN2024	Vicki Frase	17	27.1	Complete
123	Intervention	1556-47	Edinburgh (Site 1)	renal stone extracorporeal shock wave lithotripsy	05JUL2023	No	Moderate	Unrelated	.	21JUL2023	RF	Ongoing	.	SD	26	27.1	Complete
124	Intervention	1556-47	Edinburgh (Site 1)	New diagnosis of Osteoporosis	30MAY2023	No	Moderate	Unrelated	.	21JUL2023	RF	Ongoing	.	SD	15	27.1	Complete
125	Intervention	1556-49	Edinburgh (Site 1)	Chest discomfort	01MAR2024	No	Moderate	Unrelated	.	03APR2024	AH	Resolved	01MAR2024	JC	8	27.1	Complete
126	Intervention	1556-59	Edinburgh (Site 1)	New Breast Cancer R Breast	29NOV2023	No	Moderate	Unrelated	.	13MAR2024	RF	Ongoing	.	Sam Donalds	16	27.1	Complete
127	Intervention	1556-59	Edinburgh (Site 1)	Breast Cancer excision and biopsy	28DEC2023	No	Moderate	Unrelated	.	13MAR2024	RF	Resolved	28DEC2023	Sam Donalds	13	27.1	Complete
128	Intervention	1556-59	Edinburgh (Site 1)	Radiotherapy to R Breast	19FEB2024	No	Moderate	Unrelated	.	13MAR2024	RF	Resolved	23FEB2024	Sam Donalds	26	27.1	Complete
129	Intervention	1557-7	Glasgow (Site 2)	Covid-19	21AUG2022	No	Moderate	Unrelated	N/A	27SEP2022	HB	Resolved	31AUG2022	SP	11	27.1	Complete
130	Intervention	1557-8	Glasgow (Site 2)	Chest Infection	03JUL2023	No	Moderate	Unrelated	.	17AUG2023	HB	Resolved	22AUG2023	MOH	11	27.1	Complete
131	Intervention	1557-8	Glasgow (Site 2)	Itchy Rash (Lower Back)	14DEC2023	No	Moderate	Unrelated	.	28FEB2024	ML	Ongoing	.	C Dunne	24	27.1	Complete
132	Intervention	1648-14	Exeter (Site 11)	Collapsed at the pub	21SEP2022	No	Moderate	Unrelated	N/A	01FEB2025	MG	Resolved	21SEP2022	Anne McGahe	27	27.1	Complete
133	Intervention	1648-15	Exeter (Site 11)	Breast Augmentation Surgery - removal and replacement of implants	21NOV2022	No	Moderate	Unrelated	N/A	01FEB2025	MG	Ongoing	.	Anne McGahe	26	27.1	Complete
134	Intervention	1648-2	Exeter (Site 11)	Fell down 2 steps from the kitchen	01SEP2022	No	Moderate	Unrelated	N/A	01FEB2025	MG	Resolved	04SEP2022	Anne McGahe	12	27.1	Complete
135	Intervention	1648-40	Exeter (Site 11)	Legs and arms aching	01DEC2023	No	Moderate	Unrelated	.	14FEB2024	CM	Ongoing	.	ME	15	27.1	Complete
136	Intervention	1648-42	Exeter (Site 11)	Flu	24DEC2023	No	Moderate	Unrelated	.	24JAN2024	CM	Resolved	03JAN2024	ME	11	27.1	Complete
137	Intervention	1720-5	Hull (Site 15)	Supraventricular tachycardia	05APR2023	No	Moderate	Unrelated	N/A	28APR2023	MC	Resolved	28APR2023	Rachel Floc	2	27.1	Complete
138	Intervention	1884-1	Inverness (Site 5)	Itchy rash to face	06JAN2023	No	Moderate	Unrelated	Unexpected	21FEB2023	JM	Ongoing	.	JM	24	27.1	Complete
139	Intervention	1884-1	Inverness (Site 5)	New Diabetes diagnosis	13MAR2023	No	Moderate	Unrelated	Unexpected	21APR2023	Clare Bradl	Ongoing	.	Joanna Math	14	27.1	Complete
140	Intervention	1884-1	Inverness (Site 5)	Anaemia	05JUL2023	No	Moderate	Unrelated	.	21JUL2023	J-M	Ongoing	.	J-M	1	27.1	Complete
141	Intervention	1889-8	Bradford (Site 7)	sob	02NOV2023	No	Moderate	Unrelated	.	02NOV2023	UM	Resolved	09NOV2023	Kim Storton	23	27.1	Complete

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142	Intervention	2176-1	Newcastle (Site 10)	Allergic reaction. Medication patches causing skin allergies.	.	No	Moderate	Unrelated	.	05DEC2023	HU	Resolved	.	KM	10	27.1	Complete
143	Intervention	2176-10	Newcastle (Site 10)	Left sided pleuritic chest pain	15APR2024	No	Moderate	Unrelated	.	22APR2024	HU	Ongoing	.	KM	23	27.1	Complete
144	Intervention	3040-3	Aberdeen (site 25)	Inflammatory Arthritis	19APR2023	No	Moderate	Unrelated	.	04AUG2023	DM	Ongoing	.	SM	15	27.1	Complete
145	Intervention	1556-34	Edinburgh (Site 1)	Sore throat	11FEB2023	No	Moderate	Possibly related	Expected	13FEB2023	AH	Resolved	22FEB2023	SD	23	27.1	Complete
146	Intervention	1556-54	Edinburgh (Site 1)	when using HTS neb brings up large amount of sputum also small amount of vo	01FEB2024	No	Moderate	Possibly related	Expected	16APR2024	AH	Resolved	08APR2024	KC	23	27.1	Complete
147	Intervention	1648-42	Exeter (Site 11)	Pain in teeth	01AUG2023	No	Moderate	Possibly related	Unexpected	14DEC2023	CM	Resolved	08FEB2024	ME	7	27.1	Complete
148	Intervention	1720-2	Hull (Site 15)	Sore painful Mouth	28JUN2022	No	Moderate	Possibly related	Expected	26JUL2022	MC	Ongoing	.	Natalie Car	7	27.1	Complete
149	Intervention	1720-4	Hull (Site 15)	Broncospasm	24JUN2022	No	Moderate	Possibly related	Expected	11JUL2022	MC	Ongoing	.	Rachel Floc	23	27.1	Complete
150	Intervention	1884-1	Inverness (Site 5)	Cough	13JUL2022	No	Moderate	Possibly related	Expected	06SEP2022	J-F	Ongoing	.	J-F	23	27.1	Complete
151	Intervention	1556-59	Edinburgh (Site 1)	Joint pain secondary to Anastrozole	01APR2024	No	Severe	Unrelated	.	18SEP2024	R-F	Resolved	04SEP2024	JC	15	27.1	Complete
152	Intervention	1648-2	Exeter (Site 11)	Fell getting off bus - broke ribs + middle left finger	24JUN2022	No	Severe	Unrelated	N/A	01FEB2025	MG	Resolved	31JUL2022	Anne McGahe	12	27.1	Complete
153	Control	1556-56	Edinburgh (Site 1)		.	.	.	.	.	.		.	.				Complete
154	Control	1556-56	Edinburgh (Site 1)		.	.	.	.	.	.		.	.				Complete
155	Control	2909-3	Walsall (Site 24)		.	.	.	.	.	.		.	.				Complete
156	Control	1556-26	Edinburgh (Site 1)	Fall secondary to leg weakness, hyponatraemia	10AUG2023	Yes	Moderate	Unrelated	.	30AUG2023	RF	Resolved	12AUG2023	SD	14	27.1	Complete
157	Control	1556-38	Edinburgh (Site 1)	Right frontal lobe infarct	06NOV2023	Yes	Moderate	Unrelated	.	29NOV2023	RF	Resolved	14NOV2023	SD	17	27.1	Complete
158	Control	1556-66	Edinburgh (Site 1)	Community Aquired pneumonia	26MAR2024	Yes	Moderate	Unrelated	.	16APR2024	RF	Resolved	08APR2024	SD	11	27.1	Complete
159	Control	1648-6	Exeter (Site 11)	PR Bleed + Abdo pain	17JUN2022	Yes	Moderate	Unrelated	N/A	04FEB2025	MG	Ongoing	.	Anne McGahe	7	27.1	Complete

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160	Control	1648-6	Exeter (Site 11)	Severe abdo pain - constipation	18AUG2022	Yes	Moderate	Unrelated	.	04FEB2025	MG	Resolved	23AUG2022	AM	7	27.1	Complete
161	Control	2176-6	Newcastle (Site 10)	New atrial flutter with decompensated heart failure	15MAY2023	Yes	Moderate	Unrelated	.	06JUN2023	ADS	.	.	K McRoberts	2	27.1	Complete
162	Control	2177-5	Princess Royal (Site 16)	Pancreatitis	16SEP2023	Yes	Moderate	Unrelated	.	05OCT2023	LL	Resolved	21SEP2023	A. Posada	7	27.1	Complete
163	Control	2972-1	East Cheshire (site 23)	inflammatory arthropathy left wrist	25SEP2023	Yes	Moderate	Unrelated	.	28SEP2023	TN	Resolved	20OCT2023	Katherine R	15	27.1	Complete
164	Control	2972-1	East Cheshire (site 23)	COPD exacerbation secondary to vaccine related illness.	21OCT2023	Yes	Moderate	Unrelated	.	27OCT2023	TN	Resolved	08NOV2023	Katherine R	23	27.1	Complete
165	Control	2972-1	East Cheshire (site 23)	ED admission post endoscopy	12DEC2023	Yes	Moderate	Unrelated	.	15DEC2023	TN	Resolved	15DEC2023	Katherine R	13	27.1	Complete
166	Control	1641-1	Wishaw (Site 4)	covid-19	17OCT2022	Yes	Severe	Unrelated	N/A	03NOV2022	MP	Resolved	23OCT2022	A Brown	11	27.1	Complete
167	Control	2972-1	East Cheshire (site 23)	Fractured Vertebrae	12JAN2024	Yes	Severe	Unrelated	.	18JAN2024	Dr T Nagara	Resolved	26APR2024	Jan Tomkins	12	27.1	Complete
168	Control	1556-38	Edinburgh (Site 1)	Duodenal Ulcer	22OCT2023	Yes	Severe	Possibly related	Unexpected	29NOV2023	RF	Resolved	02NOV2023	SD	7	27.1	Complete
169	Control	2909-4	Walsall (Site 24)	Urinary Tract Infection	22FEB2024	No	.	.	.	11MAR2024	KI	Resolved	27FEB2024	R Chadwick	11	27.1	Complete
170	Control	1648-26	Exeter (Site 11)	Raised LFT's - from bloods taken to check clotting factors rom leg bruise	02JAN2023	No	.	Unrelated	N/A	01FEB2025	MG	Ongoing	.	Anne McGahe	13	27.1	Complete
171	Control	1648-26	Exeter (Site 11)	Liver Ultrasound - No abnormality seen	27APR2023	No	.	Unrelated	N/A	01FEB2025	MG	Resolved	27APR2023	Anne McGahe	13	27.1	Complete
172	Control	2909-4	Walsall (Site 24)	Chest Infection	18FEB2024	No	.	.	.	11MAR2024	KI	Resolved	10MAR2024	R Chadwick	11	27.1	Complete
173	Control	1556-17	Edinburgh (Site 1)	Urinary tract infection	10NOV2022	No	Mild	Unrelated	N/A	09JAN2023	RF	Resolved	17NOV2022	Sam Donalds	11	27.1	Complete
174	Control	1556-21	Edinburgh (Site 1)	Infection Left ankle at site of old metal work	01MAY2023	No	Mild	Unrelated	N/A	10MAY2023	RF	Ongoing	.	SD	11	27.1	Complete
175	Control	1556-3	Edinburgh (Site 1)	viral illness	15JAN2022	No	Mild	Unrelated	N/A	08FEB2022	RF	Resolved	08FEB2022	SD	11	27.1	Complete
176	Control	1556-30	Edinburgh (Site 1)	Worsening of Ryanaud's	19MAR2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	04APR2023	SD	27	27.1	Complete
177	Control	1556-30	Edinburgh (Site 1)	Worsening of visual migraines	31JAN2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	04APR2023	SD	17	27.1	Complete

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178	Control	1556-30	Edinburgh (Site 1)	Intermittent Nosebleeds	31JAN2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	10MAY2023	SD	23	27.1	Complete
179	Control	1556-30	Edinburgh (Site 1)	Very Yellow urine	06FEB2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	06APR2023	SD	21	27.1	Complete
180	Control	1556-30	Edinburgh (Site 1)	Increased pain in joints	20FEB2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	10MAY2023	SD	15	27.1	Complete
181	Control	1556-30	Edinburgh (Site 1)	Reduced strength in joints	20FEB2023	No	Mild	Unrelated	N/A	21MAR2023	AH	Resolved	10MAY2023	SD	8	27.1	Complete
182	Control	1556-37	Edinburgh (Site 1)	Fungal Nail infection	02AUG2023	No	Mild	Unrelated	.	14NOV2023	RF	Resolved	16AUG2023	JC	11	27.1	Complete
183	Control	1556-38	Edinburgh (Site 1)	Feeling of lump in throat in throat - worse in mornings	04APR2023	No	Mild	Unrelated	N/A	25APR2023	Prof A. Hil	Ongoing	.	SD	8	27.1	Complete
184	Control	1556-48	Edinburgh (Site 1)	Urinary Frequency	04APR2023	No	Mild	Unrelated	N/A	07APR2023	Dr Ruzanna	Resolved	07APR2023	Andrea Clar	21	27.1	Complete
185	Control	1556-5	Edinburgh (Site 1)	worsening dry eyes	02FEB2022	No	Mild	Unrelated	N/A	21FEB2022	Prof A Hill	Resolved	21JUL2022	SD	6	27.1	Complete
186	Control	1556-5	Edinburgh (Site 1)	More frequent micturition	27JAN2022	No	Mild	Unrelated	N/A	05APR2022	RF	Resolved	08FEB2022	SD	21	27.1	Complete
187	Control	1556-5	Edinburgh (Site 1)	Dry mouth/throat/ difficulty swallowing	27JAN2022	No	Mild	Unrelated	N/A	05APR2022	RF	Resolved	20APR2022	SD	7	27.1	Complete
188	Control	1556-60	Edinburgh (Site 1)	Headaches	24OCT2023	No	Mild	Unrelated	.	29NOV2023	RF	Resolved	29NOV2023	SD	17	27.1	Complete
189	Control	1556-60	Edinburgh (Site 1)	Depression	24OCT2023	No	Mild	Unrelated	.	29NOV2023	RF	Resolved	29NOV2023	SD	20	27.1	Complete
190	Control	1556-61	Edinburgh (Site 1)	Soft tissue injury pelvis	22NOV2023	No	Mild	Unrelated	.	22NOV2023	RF	Resolved	22NOV2023	SD	12	27.1	Complete
191	Control	1556-65	Edinburgh (Site 1)	Chest pain	11NOV2024	No	Mild	Unrelated	.	18NOV2024	RF	Resolved	11NOV2024	SD	8	27.1	Complete
192	Control	1556-65	Edinburgh (Site 1)	Atrial Fibrillation	11NOV2024	No	Mild	Unrelated	.	18NOV2024	RF	Ongoing	.	SD	2	27.1	Complete
193	Control	1556-9	Edinburgh (Site 1)	Shingles	15JUL2022	No	Mild	Unrelated	N/A	23AUG2022	RF	Resolved	04SEP2022	SD	11	27.1	Complete
194	Control	1556-9	Edinburgh (Site 1)	Covid-19	16AUG2022	No	Mild	Unrelated	N/A	23AUG2022	RF	Resolved	23AUG2022	SD	11	27.1	Complete
195	Control	1557-11	Glasgow (Site 2)	Nausea	30JUL2023	No	Mild	Unrelated	.	18AUG2023	HB	Resolved	31JUL2023	C Dunne	7	27.1	Complete
196	Control	1557-11	Glasgow (Site 2)	Covid	31AUG2023	No	Mild	Unrelated	.	22SEP2023	L Davidson	Resolved	06SEP2023	C Dunne	11	27.1	Complete
197	Control	1557-11	Glasgow (Site 2)	Possible Covid	27JUN2024	No	Mild	Unrelated	.	03JUL2024	M Lumsden	Resolved	15JUL2024	C Dunne	11	27.1	Complete
198	Control	1557-4	Glasgow (Site 2)	Arthritis in Fingers and Wrists	01JUN2022	No	Mild	Unrelated	N/A	14OCT2022	HB	Ongoing	.	David Jenki	15	27.1	Complete

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199	Control	1641-2	Wishaw (Site 4)	rectal discomfort	26JUN2023	No	Mild	Unrelated	.	25JUL2023	AS	Ongoing	.	A Brown	7	27.1	Complete
200	Control	1645-5	Birmingham Good Hope (Site 13)	Participant experienced a urinary tract infection. Phoned NHS 111 (as advis	28JUL2023	No	Mild	Unrelated	.	05SEP2023	BA	Resolved	30JUL2023	AR	11	27.1	Complete
201	Control	1648-1	Exeter (Site 11)	Inflammation of rotation cuff, right shoulder	20MAY2022	No	Mild	Unrelated	N/A	01FEB2025	MG	Ongoing	.	Anne McGahe	15	27.1	Complete
202	Control	1648-26	Exeter (Site 11)	Gout	20JUL2023	No	Mild	Unrelated	.	25OCT2023	CM	Ongoing	.	ME	14	27.1	Complete
203	Control	1648-26	Exeter (Site 11)	Discomfort/pain in joints on left arm	10NOV2023	No	Mild	Unrelated	.	27NOV2023	CM	Ongoing	.	ME	15	27.1	Complete
204	Control	1648-46	Exeter (Site 11)	Covid19	24DEC2023	No	Mild	Unrelated	.	24JAN2024	CM	Resolved	31DEC2023	ME	11	27.1	Complete
205	Control	1648-46	Exeter (Site 11)	Alzheimers	20MAR2024	No	Mild	Unrelated	.	26JUL2024	CM	Ongoing	.	ME	17	27.1	Complete
206	Control	1648-46	Exeter (Site 11)	Constipation	21AUG2024	No	Mild	Unrelated	.	01OCT2024	MG	Ongoing	.	ME	7	27.1	Complete
207	Control	1648-46	Exeter (Site 11)	coughing	13OCT2024	No	Mild	Unrelated	.	22OCT2024	MG	Ongoing	.	ME	23	27.1	Complete
208	Control	1648-6	Exeter (Site 11)	Earache	09NOV2022	No	Mild	Unrelated	.	04FEB2025	MG	Ongoing	.	AM	4	27.1	Complete
209	Control	1720-1	Hull (Site 15)	covid-19 infection	28MAR2022	No	Mild	Unrelated	N/A	28MAR2022	MC	Resolved	06APR2022	R Flockton	11	27.1	Complete
210	Control	1720-1	Hull (Site 15)	covid-19 infection	20JUN2022	No	Mild	Unrelated	N/A	17AUG2022	MC	Resolved	29JUN2022	R Flockton	11	27.1	Complete
211	Control	1720-1	Hull (Site 15)	pre-syncope	06SEP2022	No	Mild	Unrelated	N/A	15SEP2022	MC	Resolved	09SEP2022	Rachel Floc	17	27.1	Complete
212	Control	1720-1	Hull (Site 15)	Infected cyst	25NOV2022	No	Mild	Unrelated	N/A	07FEB2023	MC	Resolved	02DEC2022	Rachel Floc	11	27.1	Complete
213	Control	1720-1	Hull (Site 15)	covid-19 infection	14DEC2022	No	Mild	Unrelated	N/A	19DEC2022	MC	Resolved	07FEB2023	Rachel Floc	11	27.1	Complete
214	Control	1884-3	Inverness (Site 5)	Chest / sternum pain	01MAR2023	No	Mild	Unrelated	Unexpected	08MAR2023	JM	Ongoing	.	Joanna Math	8	27.1	Complete
215	Control	1884-4	Inverness (Site 5)	Fracture right hand	21FEB2023	No	Mild	Unrelated	Unexpected	06MAR2023	JF	Resolved	14MAR2023	Joanna Math	12	27.1	Complete
216	Control	1884-4	Inverness (Site 5)	Urinary tract infection	02FEB2023	No	Mild	Unrelated	Unexpected	06MAR2023	JM	Resolved	05FEB2023	Joanna Math	11	27.1	Complete
217	Control	1884-4	Inverness (Site 5)	paroxysmal atrial fibrillation	03JAN2024	No	Mild	Unrelated	.	15JAN2024	J-F	Ongoing	.	Jim Finlays	2	27.1	Complete
218	Control	1884-8	Inverness (Site 5)	Covid 19	11NOV2023	No	Mild	Unrelated	.	06DEC2023	J-F	Resolved	19NOV2023	Joanna Math	11	27.1	Complete
219	Control	1889-1	Bradford (Site 7)	Fall	14AUG2023	No	Mild	Unrelated	.	14AUG2023	UM	Resolved	23AUG2023	Deborah Coo	12	27.1	Complete

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
220	Control	2176-4	Newcastle (Site 10)	Skin and Subcutaneous Tissue - other: 'Dark Spots'	15DEC2022	No	Mild	Unrelated	Unexpected	22DEC2022	Dr Georgia	Ongoing	.	Kate McRobe	24	27.1	Complete
221	Control	2176-4	Newcastle (Site 10)	Low energy	.	No	Mild	Unrelated	.	20SEP2023	ADS	Ongoing	.	K McRoberts	8	27.1	Complete
222	Control	2176-4	Newcastle (Site 10)	Increased breathlessness	.	No	Mild	Unrelated	.	20SEP2023	ADS	Ongoing	.	K McRoberts	23	27.1	Complete
223	Control	2176-6	Newcastle (Site 10)	Folate deficiency	13FEB2023	No	Mild	Unrelated	Unexpected	15FEB2023	GT	Ongoing	.	Kate McRobe	14	27.1	Complete
224	Control	2176-6	Newcastle (Site 10)	Blepharitis	15MAR2023	No	Mild	Unrelated	Unexpected	16MAR2023	GT	Ongoing	.	Kate McRobe	6	27.1	Complete
225	Control	2176-6	Newcastle (Site 10)	increased urinary symptoms	25MAR2023	No	Mild	Unrelated	Unexpected	28MAR2023	GT	Ongoing	.	K McRoberts	21	27.1	Complete
226	Control	2176-8	Newcastle (Site 10)	Allergic reaction to antibiotics prescribed by GP. Swollen hands and wheezi	06JUN2023	No	Mild	Unrelated	.	20JUN2023	ADS	Resolved	13JUN2023	KM	10	27.1	Complete
227	Control	2176-8	Newcastle (Site 10)	Swollen leg. Left leg erythematous ?DVT NAD. USS on day admission	03AUG2023	No	Mild	Unrelated	.	09AUG2023	TDS	Resolved	.	KM	8	27.1	Complete
228	Control	2176-8	Newcastle (Site 10)	Red sore to touch left leg following previous left leg infection	28SEP2023	No	Mild	Unrelated	.	17OCT2023	ADS	Ongoing	.	K McRoberts	11	27.1	Complete
229	Control	2176-8	Newcastle (Site 10)	Flu symptoms	16NOV2023	No	Mild	Unrelated	.	28NOV2023	HU	Resolved	27NOV2023	KM	11	27.1	Complete
230	Control	2177-1	Princess Royal (Site 16)	Right sided headache with right eye discomfort	18NOV2022	No	Mild	Unrelated	N/A	01DEC2022	LL	Resolved	15FEB2023	ACP	17	27.1	Complete
231	Control	2177-3	Princess Royal (Site 16)	Pulmonary Embolism	09AUG2023	No	Mild	Unrelated	.	15AUG2023	LL	Resolved	30AUG2024	ES	23	27.1	Complete
232	Control	2177-5	Princess Royal (Site 16)	Fall	28JUL2023	No	Mild	Unrelated	.	04AUG2023	ED	Resolved	04AUG2023	E. Strak	12	27.1	Complete
233	Control	2178-2	Fife (Site 18)	Otitis externa / Ear inflammation	20DEC2023	No	Mild	Unrelated	.	18JAN2024	SF	Resolved	29FEB2024	Anne Marie	4	27.1	Complete
234	Control	2178-2	Fife (Site 18)	Otitis Externa / Ear inflammation	15MAR2024	No	Mild	Unrelated	.	15MAR2024	SF	Ongoing	.	Anne Marie	4	27.1	Complete
235	Control	2909-3	Walsall (Site 24)	Flu-like Symptoms	14OCT2023	No	Mild	Unrelated	.	25OCT2023	KI	Resolved	16OCT2023	R Chadwick	8	27.1	Complete
236	Control	2909-4	Walsall (Site 24)	Left Eye Infection	24NOV2023	No	Mild	Unrelated	.	07DEC2023	KI	Resolved	12DEC2023	R Chadwick	11	27.1	Complete

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
237	Control	3040-2	Aberdeen (site 25)	Disturbed sleep	27MAR2023	No	Mild	Unrelated	N/A	04APR2023	DM	Resolved	01AUG2023	VF	20	27.1	Complete
238	Control	3040-2	Aberdeen (site 25)	Dry lips	27MAR2023	No	Mild	Unrelated	N/A	04APR2023	DM	Resolved	01AUG2023	VF	7	27.1	Complete
239	Control	3040-2	Aberdeen (site 25)	Dizzy spells	28MAR2023	No	Mild	Unrelated	N/A	31MAY2023	CKRW	Resolved	27JUN2023	VF	17	27.1	Complete
240	Control	3040-2	Aberdeen (site 25)	Very Bad Flatulence	11APR2023	No	Mild	Unrelated	N/A	31MAY2023	CKRW	Resolved	01AUG2023	VF	7	27.1	Complete
241	Control	3040-2	Aberdeen (site 25)	Hot and cold flushes	11APR2023	No	Mild	Unrelated	N/A	31MAY2023	CKRW	Resolved	01AUG2023	VF	8	27.1	Complete
242	Control	3040-2	Aberdeen (site 25)	Anxiety	02MAY2023	No	Mild	Unrelated	N/A	31MAY2023	CKRW	Resolved	01AUG2023	VF	20	27.1	Complete
243	Control	3040-2	Aberdeen (site 25)	Dental Infection	20JUN2023	No	Mild	Unrelated	.	25JUL2023	CRWK	Resolved	23SEP2023	SM	11	27.1	Complete
244	Control	3040-2	Aberdeen (site 25)	Tooth Extraction	23SEP2023	No	Mild	Unrelated	.	12OCT2023	DM	Resolved	23SEP2023	SM	26	27.1	Complete
245	Control	3040-2	Aberdeen (site 25)	Pain from tooth extraction	23SEP2023	No	Mild	Unrelated	.	12OCT2023	DM	Resolved	07OCT2023	SM	7	27.1	Complete
246	Control	3040-8	Aberdeen (site 25)	Cold Symptoms	08SEP2023	No	Mild	Unrelated	.	08NOV2023	CRWK	Resolved	15SEP2023	SM	11	27.1	Complete
247	Control	3040-8	Aberdeen (site 25)	Colonoscopy	16OCT2023	No	Mild	Unrelated	.	08NOV2023	CRWK	Resolved	16OCT2023	SM	13	27.1	Complete
248	Control	1556-30	Edinburgh (Site 1)	Small red rash on back forearms	14MAR2023	No	Mild	Possibly related	Expected	21MAR2023	AH	Resolved	30APR2023	SD	24	27.1	Complete
249	Control	1556-30	Edinburgh (Site 1)	rash on arms and legs	03MAY2023	No	Mild	Possibly related	Expected	10MAY2023	RF	Resolved	10MAY2023	SD	24	27.1	Complete
250	Control	1556-37	Edinburgh (Site 1)	Urticaria	07MAR2023	No	Mild	Possibly related	Expected	03APR2023	RF	Ongoing	.	SD	24	27.1	Complete
251	Control	1556-67	Edinburgh (Site 1)	Skin rash - arms, stomach, groin and legs	06DEC2023	No	Mild	Possibly related	Expected	18DEC2023	RF	Resolved	22DEC2023	SD	24	27.1	Complete
252	Control	1641-2	Wishaw (Site 4)	abdominal discomfort	21JUL2023	No	Mild	Possibly related	Expected	25JUL2023	AS	Ongoing	.	A Brown	7	27.1	Complete
253	Control	1646-5	Birmingham Heartlands (Site 12)	Cough	12AUG2024	No	Mild	Possibly related	N/A	26SEP2024	SK	Resolved	31AUG2024	Susan Renwi	23	27.1	Complete
254	Control	1884-3	Inverness (Site 5)	Cough	10JAN2023	No	Mild	Possibly related	Unexpected	23JAN2023	JF	Ongoing	.	Dr Jim Finl	23	27.1	Complete
255	Control	1884-4	Inverness (Site 5)	Dry mouth	23MAR2023	No	Mild	Possibly related	Unexpected	04MAY2023	J-M	Ongoing	.	J-M	7	27.1	Complete
256	Control	2177-1	Princess Royal (Site 16)	Itchy scalp	18NOV2022	No	Mild	Possibly related	Unexpected	01DEC2022	LL	Resolved	15FEB2023	ACP	24	27.1	Complete
257	Control	2177-3	Princess Royal (Site 16)	Diarrhea	26JUN2023	No	Mild	Possibly related	Unexpected	20JUL2023	ED	Resolved	07NOV2023	ACP	8	27.1	Complete

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
258	Control	2177-3	Princess Royal (Site 16)	Nausea	17AUG2023	No	Mild	Possibly related	Expected	22AUG2023	LL	Resolved	07NOV2023	ES	7	27.1	Complete
259	Control	2909-4	Walsall (Site 24)	Chest Pain	19DEC2023	No	Mild	Possibly related	Expected	11JAN2024	IK	Resolved	20DEC2023	Ben Jones	8	27.1	Complete
260	Control	3040-1	Aberdeen (site 25)	Reflux	10MAR2023	No	Mild	Possibly related	Expected	04APR2023	DM	Resolved	13MAR2023	Vicki Frase	7	27.1	Complete
261	Control	3040-2	Aberdeen (site 25)	Nausea, abdominal pain	25MAR2023	No	Mild	Possibly related	Expected	04APR2023	DM	Resolved	01AUG2023	VF	7	27.1	Complete
262	Control	3040-2	Aberdeen (site 25)	Soft stool	30MAR2023	No	Mild	Possibly related	Expected	04APR2023	DM	Resolved	01AUG2023	VF	7	27.1	Complete
263	Control	3040-4	Aberdeen (site 25)	Coughing	19APR2023	No	Mild	Possibly related	Unexpected	09JUN2023	DM	Resolved	24MAY2023	VF	23	27.1	Complete
264	Control	1556-19	Edinburgh (Site 1)	Epistaxis	24MAR2023	No	Moderate	Unrelated	Unexpected	05APR2023	AH	Resolved	25MAR2023	JC	23	27.1	Complete
265	Control	1556-26	Edinburgh (Site 1)	Right midshaft calvicle fracture	06SEP2023	No	Moderate	Unrelated	.	17JAN2024	RF	Resolved	19OCT2023	AC	12	27.1	Complete
266	Control	1556-37	Edinburgh (Site 1)	Fall	09NOV2023	No	Moderate	Unrelated	.	12FEB2024	RF	Resolved	16NOV2023	Andrea Clar	12	27.1	Complete
267	Control	1556-53	Edinburgh (Site 1)	Fall	25DEC2023	No	Moderate	Unrelated	.	01FEB2024	RF	Resolved	25DEC2023	Andrea Clar	12	27.1	Complete
268	Control	1556-60	Edinburgh (Site 1)	Abdominal rash - eczema	08JUN2024	No	Moderate	Unrelated	.	11SEP2024	RF	Resolved	23JUL2024	JC	24	27.1	Complete
269	Control	1556-66	Edinburgh (Site 1)	Hand injury from garden fork piercing	12NOV2024	No	Moderate	Unrelated	.	10DEC2024	AH	Resolved	14NOV2024	JC	12	27.1	Complete
270	Control	1557-11	Glasgow (Site 2)	Chest Pain and Left Arm Pain	27FEB2024	No	Moderate	Unrelated	.	08MAR2024	LD	Resolved	29FEB2024	CDunne	8	27.1	Complete
271	Control	1641-2	Wishaw (Site 4)	rash	05OCT2023	No	Moderate	Unrelated	.	09NOV2023	MP	Resolved	11DEC2023	ABrown	24	27.1	Complete
272	Control	1641-2	Wishaw (Site 4)	back pain	15FEB2024	No	Moderate	Unrelated	.	11APR2024	AS	Ongoing	.	A Brown	15	27.1	Complete
273	Control	1648-12	Exeter (Site 11)	Migraine	26SEP2022	No	Moderate	Unrelated	Expected	01FEB2025	MG	Resolved	04OCT2022	Anne McGahe	17	27.1	Complete
274	Control	1648-17	Exeter (Site 11)	Fall	24FEB2023	No	Moderate	Unrelated	N/A	01FEB2025	MG	Resolved	17MAR2023	Anne McGahe	12	27.1	Complete
275	Control	1648-17	Exeter (Site 11)	Fall	22OCT2022	No	Moderate	Unrelated	.	01FEB2025	MG	Resolved	13MAR2023	AM	12	27.1	Complete
276	Control	1648-26	Exeter (Site 11)	Bruised lower L leg - bloods taken for clotting	.	No	Moderate	Unrelated	.	01FEB2025	MG	Resolved	.	AM	12	27.1	Complete
277	Control	1648-30	Exeter (Site 11)	Fall - hit head	20OCT2023	No	Moderate	Unrelated	.	27OCT2023	CM	Resolved	24OCT2023	ME	12	27.1	Complete
278	Control	1884-4	Inverness (Site 5)	Loss of consciousness - Syncope vasovagal	20APR2023	No	Moderate	Unrelated	Unexpected	02MAY2023	J-M	Ongoing	.	Jim Finlays	17	27.1	Complete

	Randomisation Result	Record ID	Data Access Group	Adverse Event	Start Date	SAE	Severity	Causality	Expectedness	Date of Assessment	Initials of Delegated Clinician	Outcome	Date Resolved	AE Recorded By	MedDRA Code (Number)	Version of MedDRA Used	Complete?
279	Control	1884-4	Inverness (Site 5)	Narrow complex tachycardia	10AUG2023	No	Moderate	Unrelated	.	24AUG2023	J-M	Resolved	10AUG2023	Clare Bradl	2	27.1	Complete
280	Control	1884-7	Inverness (Site 5)	Head cold	26OCT2023	No	Moderate	Unrelated	.	20DEC2023	J-F	Ongoing	.	Jim Finlays	11	27.1	Complete
281	Control	1889-1	Bradford (Site 7)	chest infection	09JAN2023	No	Moderate	Unrelated	Expected	17JAN2023	UM	Resolved	15JAN2023	Kim Storton	11	27.1	Complete
282	Control	1889-1	Bradford (Site 7)	chest infection	14MAR2023	No	Moderate	Unrelated	N/A	14MAR2023	UM	Resolved	19MAR2023	Kim Storton	11	27.1	Complete
283	Control	1889-1	Bradford (Site 7)	elective admission for left lower lid entropion correction	17OCT2023	No	Moderate	Unrelated	.	17OCT2023	UM	Resolved	24OCT2023	Dominika Mi	26	27.1	Complete
284	Control	1889-2	Bradford (Site 7)	sinusitis	20JUL2023	No	Moderate	Unrelated	.	20JUL2023	UM	Resolved	27JUL2023	Kim Storton	11	27.1	Complete
285	Control	1889-2	Bradford (Site 7)	enlarged prostate	25AUG2023	No	Moderate	Unrelated	.	25AUG2023	UM	Ongoing	.	Dominika Mi	22	27.1	Complete
286	Control	2176-4	Newcastle (Site 10)	Covid positive	.	No	Moderate	Unrelated	.	02AUG2023	ADS	Resolved	.	K McRoberts	11	27.1	Complete
287	Control	3040-2	Aberdeen (site 25)	Very lethargic	18APR2023	No	Moderate	Unrelated	N/A	31MAY2023	CKRW	Resolved	01AUG2023	VF	17	27.1	Complete
288	Control	3040-2	Aberdeen (site 25)	Abdominal Pain	18APR2023	No	Moderate	Unrelated	N/A	31MAY2023	CKRW	Resolved	04OCT2023	VF	7	27.1	Complete
289	Control	3040-2	Aberdeen (site 25)	Possible drug reaction	20JUN2023	No	Moderate	Possibly related	Expected	26JUL2023	CRWK	Resolved	01AUG2023	SM	10	27.1	Complete

Adverse events

Line listing of serious adverse events

	Treatment group	Record ID	Reporter seriousness	Reporter severity	Reporter causality	Received date	Latest received	Suspect drug	Primary event	Date of onset	Date of resolution	Action taken	Event serious criteria	Date of death	Outcome	SOC
1	Nebulised 7% Saline + ABCT (Intervention)	1556-55	Serious	Severe	Unrelated	01MAY2024	05JUN 2024	7% Hypertonic Saline	fractured neck of femur	24APR2024	28MAY2024	IMP dose not changed	Death, Hospitalisation	28MAY24:00:00	Death	Injury, poisoning and procedural complications
2	Nebulised 7% Saline + ABCT (Intervention)	1556-57	Serious	Moderate	Unrelated	17NOV2023	13DEC 2023	Hypertonic Saline 7%	Community Acquired Pneumonia	13NOV2023	19NOV2023	IMP dose reduced	Hospitalisation	.	Completely Recovered	Infections and infestations
3	Nebulised 7% Saline + ABCT (Intervention)	1556-63	Serious	Moderate	Unrelated	12DEC2023	31JAN 2024	Hypertonic Saline	Acute Abdominal pain with vomiting and Rectal bleeding	30NOV2023	18DEC2023	IMP dose not changed	Hospitalisation	.	Completely Recovered	
4	Nebulised 7% Saline + ABCT (Intervention)	1556-63	Serious	Moderate	Unrelated	07FEB2024	.	Hypertonic saline	Acute flare up of diverticulitis	01FEB2024	02FEB2024	IMP dose not changed	Hospitalisation	.	Completely Recovered	
5	Nebulised 7% Saline + ABCT (Intervention)	1556-63	Serious	Moderate	Unrelated	19FEB2024	02MAY 2024	Hypertonic Saline 7%	Flare of diverticulitis	17FEB2024	19FEB2024	Unknown	Hospitalisation	.	Recovered with sequelae	
6	Nebulised 7% Saline + ABCT (Intervention)	1556-7	Serious	Moderate	Unrelated	07DEC2022	17JUN 2024	Hypertonic Saline 7%	Pneumonia + Flu A	05DEC2022	10DEC2022	IMP dose not changed	Hospitalisation	.	Completely Recovered	
7	Nebulised 7% Saline + ABCT (Intervention)	1557-1	Serious	Moderate	Unrelated	01SEP2022	.	7% saline ampules	Pulmonary Embolism	23AUG2022	21AUG2023	Not Applicable	Medically Significant	.	Recovered with sequelae	Respiratory, thoracic and mediastinal disorders
8	Nebulised 7% Saline + ABCT (Intervention)	1720-5	Serious	Severe	Unrelated	10APR2024	15APR 2024	Hypertonic saline 7%	NON-INFECTIVE exacerbation of COPD	05APR2023	06APR2023	Not Applicable	Death	06APR23:00:00	Death	
9	Nebulised 7% Saline + ABCT (Intervention)	2177-4	Serious	Moderate	Unrelated	14NOV2023	16NOV 2023	Saline	Spinal injury, Surgery for spinal injury	01NOV2023	10NOV2023	IMP dose not changed	Hospitalisation	.	Completely Recovered	
10	Nebulised 7% Saline + ABCT (Intervention)	3040-12	Serious	Moderate	Unrelated	18JUN2024	21AUG 2024	Sodium chloride 7% nebuliser	Acute gastroenteritis	10JUN2024	22JUL2024	IMP dose not changed	Hospitalisation	.	Completely Recovered	Infections and infestations
11	750 mg Carbocisteine + ABCT (Control)	1556-26	Serious	Moderate	Unrelated	29AUG2023	05SEP 2023	Carbocisteine	Fall secondary to leg weakness, hyponatraemia	10AUG2023	12AUG2023	IMP dose not changed	Hospitalisation	.	Completely Recovered	

	Treatment group	Record ID	Reporter seriousness	Reporter severity	Reporter causality	Received date	Latest received	Suspect drug	Primary event	Date of onset	Date of resolution	Action taken	Event serious criteria	Date of death	Outcome	SOC
12	750 mg Carbocisteine + ABCT (Control)	1556-38	Serious	Severe	Possibly Related	27NOV2023	06DEC 2023	Carbocisteine capsules	Duodenal Ulcer	22OCT2023	02NOV2023	IMP permanently discontinued	Hospitalisation	.	Completely Recovered	Gastrointestinal disorders
13	750 mg Carbocisteine + ABCT (Control)	1556-38	Serious	Moderate	Unrelated	27NOV2023	29NOV 2023	Carbocisteine	Right Frontal lobe infarct	06NOV2023	14NOV2023	Not Applicable	Hospitalisation	.	Recovered with sequelae	
14	750 mg Carbocisteine + ABCT (Control)	1556-66	Serious	Moderate	Unrelated	16APR2024	.	Carbocisteine	Community Acquired Pneumonia	26MAR2024	08APR2024	IMP dose not changed	Hospitalisation	.	Recovered with sequelae	Infections and infestations
15	750 mg Carbocisteine + ABCT (Control)	1641-1	Serious	Severe	Unrelated	03NOV2022	07DEC 2022	Carbocisteine	COVID	17OCT2022	23OCT2022	IMP dose reduced	Hospitalisation	.	Completely Recovered	
16	750 mg Carbocisteine + ABCT (Control)	1648-6	Serious	Moderate	Unrelated	04FEB2025	17FEB 2025	Carbocisteine	Viral Illness	18AUG2022	23AUG2022	IMP dose not changed	Hospitalisation	.	Completely Recovered	
17	750 mg Carbocisteine + ABCT (Control)	1648-6	Serious	Moderate		04FEB2025	17FEB 2025	no IMP administered	PR Bleeding	17JUN2022	01OCT2023	Not Applicable	Hospitalisation	.	Completely Recovered	
18	750 mg Carbocisteine + ABCT (Control)	2176-6	Serious	Moderate	Unrelated	18MAY2023	22AUG 2023	Carbosistien e	New atrial flutter with decompensated heart failure	15MAY2023	.	IMP permanently discontinued	Hospitalisation	.		
19	750 mg Carbocisteine + ABCT (Control)	2177-5	Serious	Moderate	Unrelated	26SEP2023	06OCT 2023	Carbocisteine	Pancreatitis	16SEP2023	21SEP2023	IMP dose not changed	Hospitalisation	.	Completely Recovered	Gastrointestinal disorders
20	750 mg Carbocisteine + ABCT (Control)	2972-1	Serious	Moderate	Unrelated	06OCT2023	08DEC 2023	Carbocisteine	Inflammatory arthropathy left wrist	25SEP2023	20OCT2023	Not Applicable	Hospitalisation	.	Completely Recovered	
21	750 mg Carbocisteine + ABCT (Control)	2972-1	Serious	Moderate	Unrelated	27OCT2023	08DEC 2023	Carbocisteine	COPD exacerbation secondary to vaccine related illness	21OCT2023	02NOV2023	IMP dose not changed	Medically Significant	.	Completely Recovered	
22	750 mg Carbocisteine + ABCT (Control)	2972-1	Serious	Moderate	Unrelated	15DEC2023	19JAN 2024	Carbocisteine	ED admission post endoscopy	12DEC2023	15DEC2023	IMP dose not changed	Hospitalisation	.	Completely Recovered	
23	750 mg Carbocisteine + ABCT (Control)	2972-1	Serious	Severe	Unrelated	19JAN2024	18OCT 2024	Carbocisteine	Fractured Vertebrae	12JAN2024	.	IMP dose not changed	Hospitalisation	.	Condition still present and unchanged	