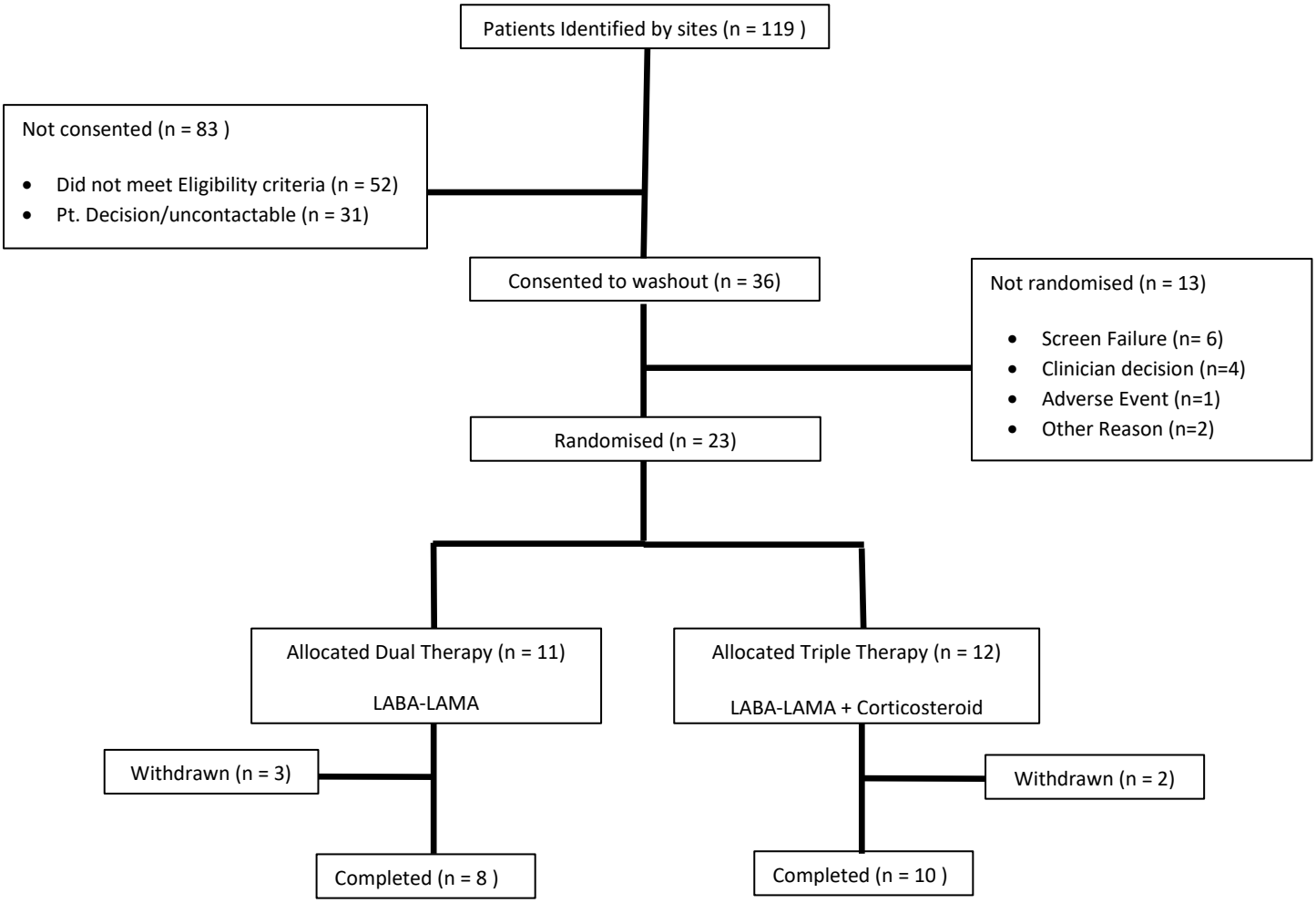
THE MICROBIAL EFFECT OF INHALED STEROIDS IN SEVERE COPD PATIENTS WITH ASSOCIATED BRONCHIECTASIS

Tempestas Clinical Trial

Basic Results Summary

01 Dec 2025

Participant Flow



Baseline characteristics

The results of the trial are summarised below.

Characteristic	Patients Included = 36
Gender: no (%)	
Male	21 (58%)
Female	15 (42%)
Age: years	
Mean (sd)	71.6 (7.0)
Ethnicity:	
White	36 (100%)
SIMD (Scottish Index of Multiple Deprivation)	
1	8 (22%)
2	13 (36%)
3	5 (14%)
4	5 (14%)
5	5 (14%)
Employment Status: currently employed? no (%)	
No	34 (94%)
Yes	2 (6%)
Occupational exposure (dust particles): no (%)	
No	25 (69%)
Yes	11 (31%)

Current alcohol use?	
No	19 (53%)
Yes	17 (47%)
Smoking:	
Current smoker	13 (36%)
Ex-Smoker (stopped smoking for at least 6 months prior to visit)	23 (64%)
Significant Medical/Surgical History:	
No	14 (39%)
Yes	20 (56%)
mMRC Score:	
1 - I get short of breath when hurrying or walking up a slight hill	5 (14%)
2 - I walk slower than other people of the same age on the level due to shortness of breath or have to stop for breath when walking at own pace on the level	11 (31%)
3 - I stop for breath after walking for a few minutes on the level or for about 100 yards or after a few minutes on the level	19 (53%)
4 - I am too breathless to leave the house	1 (3%)
COPD Status (Based on GOLD Classification)	
C - Low symptoms, high risk	1 (3%)
D - High symptoms, high risk	35 (97%)
ECG Result	
Normal	27 (75%)
Abnormal	9 (25%)

Primary Outcome

The primary outcome was to measure a baseline to 1-year change (expressed in log units) in colony forming units per ml (CFU/mL) between treatment arms (LABA-LAMA plus corticosteroid versus LABA-LAMA only) .

A comparison between treatment arms for baseline to 1-year change in log (CFU m/l) has been conducted using a two-sample t-test.

N.B. Given that we are prior to publication, further details cannot be provided due to the nature of the results.

Adverse events

	Randomised treatment						Total	
	Not randomised		Dual Therapy		Triple Therapy			
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Total number of participants	13	100	11	100	12	100	36	100
Any AEs	6	46	2	18	2	17	10	28
No								
Yes	7	54	9	82	10	83	26	72
Total number of AE	6	46	2	18	2	17	10	28
0								
1	6	46	4	36	2	17	12	33
2	1	8	2	18	2	17	5	14
3	.	.	.	.	3	25	3	8
4	.	.	2	18	2	17	4	11
5	.	.	.	.	1	8	1	3
9	.	.	1	9	.	.	1	3

	Randomised treatment						Total	
	Not randomised		Dual Therapy		Triple Therapy			
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Total number of AEs	8	100	25	100	27	100	60	100
Causality	6	75	17	68	21	78	44	73
Unrelated								
Possibly related	2	25	8	32	6	22	16	27
Severity	2	25	5	20	7	26	14	23
Mild								
Moderate	5	63	16	64	15	56	36	60
Severe	1	13	4	16	5	19	10	17
Expectedness	2	25	6	24	11	41	19	32
Expected								
Unexpected	1	13	6	24	3	11	10	17
N/A	5	63	13	52	13	48	31	52

Adverse Event	MedDRA Code Classification (Version	Count
Exacerbation of COPD	23. Respiratory, Thoracic, and Mediastinal Disorders	44
Pneumonia	23. Respiratory, Thoracic, and Mediastinal Disorders	2
Bronchitis	23. Respiratory, Thoracic, and Mediastinal Disorders	2
Right side pleuritic pain	23. Respiratory, Thoracic, and Mediastinal Disorders	1
Chest infection	23. Respiratory, Thoracic, and Mediastinal Disorders	1
Medical Investigation - Cystoscopy	13. Investigations	1
Lung cancer	16. Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1
Hydroureteronephrosis and pyelonephritis	11. Infections and infestations	1
Mild increase in creatinine	13. Investigations	1
Mouth thrush	11. Infections and infestations	1
Covid-19 infection	11. Infections and infestations	1
Urinary retention	21. Renal and urinary disorders	1
Hypertension	27. Vascular disorders	1
Folate deficiency anaemia	14. Metabolism and nutrition disorders	1
Myocardial infarction	2. Cardiac disorder	1