

CDAID Basic Results Summary

ISRCTN11093445

Participant Flow

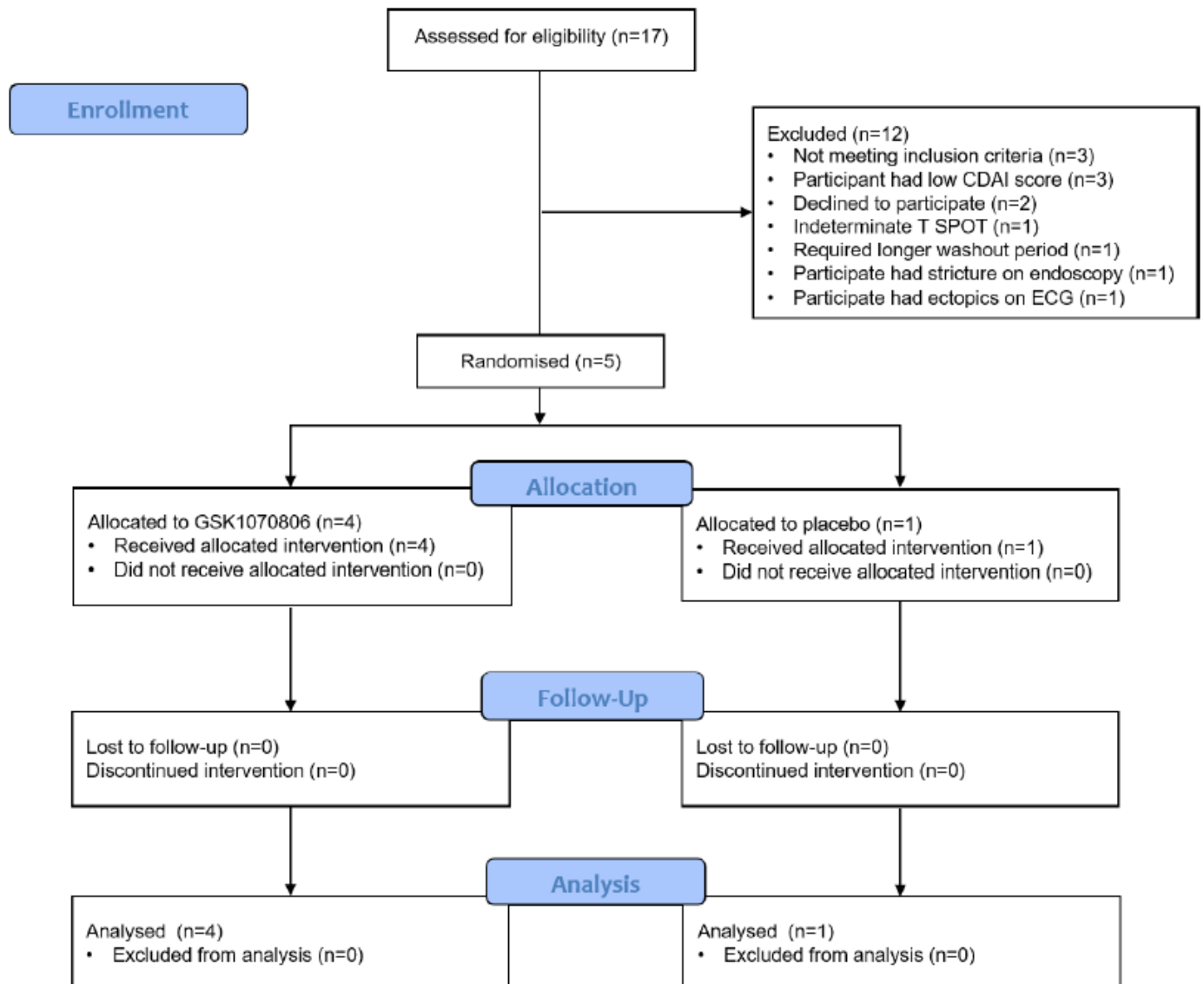


Figure 1. CONSORT diagram

Baseline Characteristics

Table 1: Summary baseline characteristics for recruited patients

	Pooled (N=5)
Age (years)	
n	5
Mean (sd)	39.4 (10.6)
Median	42
IQR	(41, 46)
Range	(21, 47)
Ethnicity (n(%))	
Asian – Indian	1 (20.00%)
Other: Asian Brit	1 (20.00%)
White - British	3 (60.00%)
Sex (n(%))	
Female	4 (80.00%)
Male	1 (20.00%)
Height (cm)	
n	5
Mean (sd)	153.36 (31.06)
Median	160
IQR	(157, 166)
Range	(100.8, 183)
Weight (kg)	
n	5
Mean (sd)	62.52 (17.04)
Median	53.1
IQR	(52.8, 78.2)
Range	(45.2, 83.3)

Outcome Measures

Primary outcome measures

1. Safety and tolerability parameters including;

a) AEs

Table 2: Summary of incidence of AEs reported during the trial per treatment allocation

	GSK1070806 (N=4)	Placebo (N=1)
N	4	1
n reporting AEs	4	1
Total AEs	114	5
Mean (sd)	28.5 (14.06)	5 (NA)
Median	30	5
IQR	(17.5, 39.5)	(5, 5)
Range	(11, 43)	(5, 5)

b) SAEs

Table 3: Summary of SAEs reported during the trial, per treatment allocation

Treatment	Category	Toxicity	Number of Patients Affected	Number of Patients Exposed	Occurrences	Number of Events Related to GSK1070806	Fatal	Related & Fatal	% Affected
GSK1070806	Gastrointestinal disorders	Abdominal pain	1	4	1	0	0	0	25%
Placebo	Gastrointestinal disorders	Abdominal pain	1	1	1	0	0	0	100%

c) Clinical laboratory tests

Table 4. Clinical laboratory results over time since registration, visits 1, 2, and 3 (Predose and 60 min post dose)

Test	Stat	Visit 1		Visit 2		Visit 3 (pre-dose)		Visit 3 (60 mins post dose)	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Alanine Transferase (ALT, U/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	26.25 (14.24)	26 ()	25.25 (11.87)	27 ()	20.5 (10.25)	37 ()	18.25 (9.57)	36 ()
	Median	30	26	29	27	23	37	20.5	36
	IQR	(17, 35.5)	(26, 26)	(18, 32.5)	(27, 27)	(14, 27)	(37, 37)	(11.5, 25)	(36, 36)
	Range	(6, 39)	(26, 26)	(8, 35)	(27, 27)	(6, 30)	(37, 37)	(5, 27)	(36, 36)
Albumin (g/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	35.25 (3.95)	43 ()	38.25 (4.72)	43 ()	36.25 (2.06)	43 ()	33.5 (2.52)	43 ()
	Median	34.5	43	36.5	43	36.5	43	34	43
	IQR	(32, 38.5)	(43, 43)	(35, 41.5)	(43, 43)	(34.5, 38)	(43, 43)	(32, 35)	(43, 43)
	Range	(32, 40)	(43, 43)	(35, 45)	(43, 43)	(34, 38)	(43, 43)	(30, 36)	(43, 43)
Alkaline Phosphatase (ALP, U/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	82 (14.09)	121 ()	88.25 (23.74)	121 ()	83.25 (21.75)	130 ()	77.25 (20.27)	135 ()
	Median	83	121	90.5	121	81	130	74.5	135
	IQR	(70, 94)	(121, 121)	(68.5, 108)	(121, 121)	(67, 99.5)	(130, 130)	(61.5, 93)	(135, 135)
	Range	(67, 95)	(121, 121)	(61, 111)	(121, 121)	(60, 111)	(130, 130)	(57, 103)	(135, 135)
APTT	n	3	1	4	1	4	1	3	1
	Mean (sd)	0.97 (0.12)	1.1 ()	0.98 (0.1)	1.1 ()	1 (0.12)	1.1 ()	0.9 (0.1)	1.1 ()
	Median	0.9	1.1	0.95	1.1	1	1.1	0.9	1.1
	IQR	(0.9, 1.1)	(1.1, 1.1)	(0.9, 1.05)	(1.1, 1.1)	(0.9, 1.1)	(1.1, 1.1)	(0.8, 1)	(1.1, 1.1)
	Range	(0.9, 1.1)	(1.1, 1.1)	(0.9, 1.1)	(1.1, 1.1)	(0.9, 1.1)	(1.1, 1.1)	(0.8, 1)	(1.1, 1.1)
Aspartate Transaminase (AST, U/L)	n	3	1	4	0	4	1	4	1
	Mean (sd)	23 (12)	34 ()	30 (14.31)	NaN ()	23.25 (7.59)	61 ()	21.5 (7.94)	45 ()
	Median	23	34	29.5		24.5	61	22.5	45
	IQR	(11, 35)	(34, 34)	(21, 39)	(, NA)	(18, 28.5)	(61, 61)	(16, 27)	(45, 45)
	Range	(11, 35)	(34, 34)	(13, 48)	(Inf, -Inf)	(13, 31)	(61, 61)	(11, 30)	(45, 45)
Basophils (10 ⁹ /L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	0.05 (0.06)	0.1 ()	0.03 (0.05)	0 ()	0.05 (0.06)	0.1 ()	0.05 (0.06)	0.1 ()
	Median	0.05	0.1	0	0	0.05	0.1	0.05	0.1
	IQR	(0, 0.1)	(0.1, 0.1)	(0, 0.05)	(0, 0)	(0, 0.1)	(0.1, 0.1)	(0, 0.1)	(0.1, 0.1)
	Range	(0, 0.1)	(0.1, 0.1)	(0, 0.1)	(0, 0)	(0, 0.1)	(0.1, 0.1)	(0, 0.1)	(0.1, 0.1)
Bilirubin (total, umol/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	7.75 (3.59)	15 ()	11.75 (5.25)	15 ()	8.25 (3.59)	13 ()	8.5 (3.11)	6 ()

Test	Stat	Visit 1		Visit 2		Visit 3 (pre-dose)		Visit 3 (60 mins post dose)	
		GSK1070806		GSK1070806		GSK1070806		GSK1070806	
		(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)
C-Reactive Protein (CRP, mg/L)	Median	6.5	15	10.5	15	7.5	13	8.5	6
	IQR	(5.5, 10)	(15, 15)	(8, 15.5)	(15, 15)	(5.5, 11)	(13, 13)	(6, 11)	(6, 6)
	Range	(5, 13)	(15, 15)	(7, 19)	(15, 15)	(5, 13)	(13, 13)	(5, 12)	(6, 6)
	n	4	1	4	1	3	1	3	1
	Mean (sd)	5.25 (4.19)	12 ()	7.75 (11.59)	12 ()	3 (3.46)	7 ()	9 (9.85)	6 ()
Calcium (mmol/L)	Median	4.5	12	2.5	12	1	7	6	6
	IQR	(2.5, 8)	(12, 12)	(1, 14.5)	(12, 12)	(1, 7)	(7, 7)	(1, 20)	(6, 6)
	Range	(1, 11)	(12, 12)	(1, 25)	(12, 12)	(1, 7)	(7, 7)	(1, 20)	(6, 6)
	n	4	1	4	1	2	1	3	1
	Mean (sd)	2.26 (0.09)	2.5 ()	2.32 (0.06)	2.56 ()	2.32 (0.06)	2.52 ()	2.22 (0.05)	2.43 ()
Creatinine (umol/L)	Median	2.26	2.5	2.31	2.56	2.32	2.52	2.24	2.43
	IQR	(2.18, 2.33)	(2.5, 2.5)	(2.27, 2.37)	(2.56, 2.56)	(2.28, 2.36)	(2.52, 2.52)	(2.17, 2.26)	(2.43, 2.43)
	Range	(2.17, 2.35)	(2.5, 2.5)	(2.26, 2.4)	(2.56, 2.56)	(2.28, 2.36)	(2.52, 2.52)	(2.17, 2.26)	(2.43, 2.43)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	68.25 (17.06)	50 ()	71 (17.78)	52 ()	63.5 (11.59)	62 ()	61 (10.33)	63 ()
eGFR (mL/min/1.7)	Median	63	50	67	52	62	62	61	63
	IQR	(58, 78.5)	(50, 50)	(60, 82)	(52, 52)	(56, 71)	(62, 62)	(53, 69)	(63, 63)
	Range	(54, 93)	(50, 50)	(54, 96)	(52, 52)	(51, 79)	(62, 62)	(49, 73)	(63, 63)
	n	3	1	4	1	3	1	3	1
	Mean (sd)	85.67 (7.51)	99 ()	84 (7.35)	99 ()	90 (0)	89 ()	88.33 (2.89)	88 ()
Eosinophils (10^9/L)	Median	90	99	85.5	99	90	89	90	88
	IQR	(77, 90)	(99, 99)	(78, 90)	(99, 99)	(90, 90)	(89, 89)	(85, 90)	(88, 88)
	Range	(77, 90)	(99, 99)	(75, 90)	(99, 99)	(90, 90)	(89, 89)	(85, 90)	(88, 88)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	0.15 (0.06)	0.2 ()	0.15 (0.06)	0 ()	0.2 (0.12)	0.1 ()	0.22 (0.15)	0.2 ()
Haematocrit (L/L)	Median	0.15	0.2	0.15	0	0.2	0.1	0.2	0.2
	IQR	(0.1, 0.2)	(0.2, 0.2)	(0.1, 0.2)	(0, 0)	(0.1, 0.3)	(0.1, 0.1)	(0.1, 0.35)	(0.2, 0.2)
	Range	(0.1, 0.2)	(0.2, 0.2)	(0.1, 0.2)	(0, 0)	(0.1, 0.3)	(0.1, 0.1)	(0.1, 0.4)	(0.2, 0.2)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	0.39 (0.04)	0.39 ()	0.39 (0.05)	0.38 ()	0.39 (0.03)	0.38 ()	0.37 (0.03)	0.37 ()
Haemoglobin (g/L)	Median	0.38	0.39	0.38	0.38	0.4	0.38	0.37	0.37
	IQR	(0.36, 0.41)	(0.39, 0.39)	(0.35, 0.42)	(0.38, 0.38)	(0.36, 0.41)	(0.38, 0.38)	(0.34, 0.4)	(0.37, 0.37)
	Range	(0.36, 0.44)	(0.39, 0.39)	(0.35, 0.44)	(0.38, 0.38)	(0.35, 0.41)	(0.38, 0.38)	(0.33, 0.4)	(0.37, 0.37)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	129.5 (12.48)	129 ()	132.75 (16.15)	129 ()	129.25 (13.23)	131 ()	123.25 (13.4)	126 ()
	Median	127	129	131.5	129	128	131	122.5	126

Test	Stat	Visit 1		Visit 2		Visit 3 (pre-dose)		Visit 3 (60 mins post dose)	
		GSK1070806		GSK1070806		GSK1070806		GSK1070806	
		(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)
INR	IQR	(120, 139)	(129, 129)	(119, 146.5)	(129, 129)	(118.5, 140)	(131, 131)	(112, 134.5)	(126, 126)
	Range	(118, 146)	(129, 129)	(118, 150)	(129, 129)	(116, 145)	(131, 131)	(110, 138)	(126, 126)
	n	3	1	4	1	4	1	3	1
	Mean (sd)	0.9 (0)	1 ()	0.92 (0.05)	1.1 ()	0.9 (0.08)	1 ()	0.9 (0)	1 ()
	Median	0.9	1	0.9	1.1	0.9	1	0.9	1
Lymphocytes (10^9/L)	IQR	(0.9, 0.9)	(1, 1)	(0.9, 0.95)	(1.1, 1.1)	(0.85, 0.95)	(1, 1)	(0.9, 0.9)	(1, 1)
	Range	(0.9, 0.9)	(1, 1)	(0.9, 1)	(1.1, 1.1)	(0.8, 1)	(1, 1)	(0.9, 0.9)	(1, 1)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	1.25 (0.42)	3 ()	1.35 (0.65)	1.9 ()	1.2 (0.45)	2.6 ()	1.38 (0.47)	2.9 ()
	Median	1.3	3	1.5	1.9	1.3	2.6	1.5	2.9
Mean Cell Haemoglobin (pg)	IQR	(0.95, 1.55)	(3, 3)	(0.85, 1.85)	(1.9, 1.9)	(0.85, 1.55)	(2.6, 2.6)	(1.1, 1.65)	(2.9, 2.9)
	Range	(0.7, 1.7)	(3, 3)	(0.5, 1.9)	(1.9, 1.9)	(0.6, 1.6)	(2.6, 2.6)	(0.7, 1.8)	(2.9, 2.9)
	n	3	1	3	1	4	1	3	1
	Mean (sd)	29 (1)	29 ()	29.67 (0.58)	30 ()	28.25 (2.22)	30 ()	29.67 (0.58)	30 ()
	Median	29	29	30	30	29	30	30	30
Mean Cell Volume (fl)	IQR	(28, 30)	(29, 29)	(29, 30)	(30, 30)	(27, 29.5)	(30, 30)	(29, 30)	(30, 30)
	Range	(28, 30)	(29, 29)	(29, 30)	(30, 30)	(25, 30)	(30, 30)	(29, 30)	(30, 30)
	n	3	1	4	1	4	1	3	1
	Mean (sd)	87 (1)	90 ()	83.5 (4.43)	89 ()	85 (4.08)	89 ()	86 (1)	89 ()
	Median	87	90	85	89	86.5	89	86	89
Monocytes (10^9/L)	IQR	(86, 88)	(90, 90)	(81, 86)	(89, 89)	(82.5, 87.5)	(89, 89)	(85, 87)	(89, 89)
	Range	(86, 88)	(90, 90)	(77, 87)	(89, 89)	(79, 88)	(89, 89)	(85, 87)	(89, 89)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	0.5 (0.08)	0.7 ()	0.5 (0.08)	0.8 ()	0.52 (0.05)	0.6 ()	0.58 (0.05)	0.7 ()
	Median	0.5	0.7	0.5	0.8	0.5	0.6	0.6	0.7
Neutrophils (10^9/L)	IQR	(0.45, 0.55)	(0.7, 0.7)	(0.45, 0.55)	(0.8, 0.8)	(0.5, 0.55)	(0.6, 0.6)	(0.55, 0.6)	(0.7, 0.7)
	Range	(0.4, 0.6)	(0.7, 0.7)	(0.4, 0.6)	(0.8, 0.8)	(0.5, 0.6)	(0.6, 0.6)	(0.5, 0.6)	(0.7, 0.7)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	3.47 (0.97)	8.6 ()	4.38 (1.48)	8.9 ()	3.52 (0.54)	6.3 ()	3.62 (0.48)	7.2 ()
	Median	3.45	8.6	4.2	8.9	3.5	6.3	3.6	7.2
Platelets (10^9/L)	IQR	(2.7, 4.25)	(8.6, 8.6)	(3.2, 5.55)	(8.9, 8.9)	(3.15, 3.9)	(6.3, 6.3)	(3.25, 4)	(7.2, 7.2)
	Range	(2.4, 4.6)	(8.6, 8.6)	(2.9, 6.2)	(8.9, 8.9)	(2.9, 4.2)	(6.3, 6.3)	(3.1, 4.2)	(7.2, 7.2)
	n	4	1	4	1	4	1	4	1
	Mean (sd)	314 (27.89)	319 ()	322.25 (34.42)	330 ()	303.5 (29.42)	334 ()	292.25 (20.43)	297 ()
	Median	317.5	319	318.5	330	300	334	294.5	297
	IQR	(295, 333)	(319, 319)	(294, 350.5)	(330, 330)	(282.5, 324.5)	(334, 334)	(275.5, 309)	(297, 297)

Test	Stat	Visit 1		Visit 2		Visit 3 (pre-dose)		Visit 3 (60 mins post dose)	
		GSK1070806		GSK1070806		GSK1070806		GSK1070806	
		(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)	(N=4)	Placebo (N=1)
	Range	(277, 344)	(319, 319)	(289, 363)	(330, 330)	(272, 342)	(334, 334)	(268, 312)	(297, 297)
Potassium (mmol/L)	n	4	1	4	1	4	1	3	0
	Mean (sd)	4.22 (0.38)	4 ()	4.12 (0.34)	4.1 ()	4.18 (0.24)	4.2 ()	3.93 (0.21)	NaN ()
	Median	4.3	4	4.05	4.1	4.1	4.2	4	
	IQR	(4, 4.45)	(4, 4)	(3.9, 4.35)	(4.1, 4.1)	(4, 4.35)	(4.2, 4.2)	(3.7, 4.1)	(, NA)
	Range	(3.7, 4.6)	(4, 4)	(3.8, 4.6)	(4.1, 4.1)	(4, 4.5)	(4.2, 4.2)	(3.7, 4.1)	(Inf, -Inf)
Red Blood Cells (10^12/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	4.53 (0.34)	4.37 ()	4.62 (0.43)	4.25 ()	4.56 (0.4)	4.3 ()	4.31 (0.38)	4.21 ()
	Median	4.46	4.37	4.65	4.25	4.72	4.3	4.39	4.21
	IQR	(4.28, 4.78)	(4.37, 4.37)	(4.31, 4.93)	(4.25, 4.25)	(4.31, 4.81)	(4.3, 4.3)	(4.04, 4.59)	(4.21, 4.21)
	Range	(4.2, 4.99)	(4.37, 4.37)	(4.08, 5.1)	(4.25, 4.25)	(3.98, 4.83)	(4.3, 4.3)	(3.79, 4.68)	(4.21, 4.21)
Sodium (mmol/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	139 (0.82)	137 ()	138 (1.83)	137 ()	137.5 (1.29)	138 ()	139 (1.83)	137 ()
	Median	139	137	138	137	137.5	138	139	137
	IQR	(138.5, 139.5)	(137, 137)	(136.5, 139.5)	(137, 137)	(136.5, 138.5)	(138, 138)	(137.5, 140.5)	(137, 137)
	Range	(138, 140)	(137, 137)	(136, 140)	(137, 137)	(136, 139)	(138, 138)	(137, 141)	(137, 137)
Total Protein (g/L)	n	4	1	4	1	3	1	3	1
	Mean (sd)	66.5 (7.05)	76 ()	71.75 (8.5)	76 ()	67.67 (2.08)	76 ()	63.33 (4.04)	76 ()
	Median	66	76	68.5	76	67	76	64	76
	IQR	(60.5, 72.5)	(76, 76)	(66, 77.5)	(76, 76)	(66, 70)	(76, 76)	(59, 67)	(76, 76)
	Range	(60, 74)	(76, 76)	(66, 84)	(76, 76)	(66, 70)	(76, 76)	(59, 67)	(76, 76)
Urea (mmol/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	3.1 (0.92)	3.3 ()	3.28 (0.28)	2.7 ()	2.62 (0.66)	2.6 ()	2.58 (0.47)	2.5 ()
	Median	3	3.3	3.25	2.7	2.65	2.6	2.7	2.5
	IQR	(2.35, 3.85)	(3.3, 3.3)	(3.05, 3.5)	(2.7, 2.7)	(2.2, 3.05)	(2.6, 2.6)	(2.3, 2.85)	(2.5, 2.5)
	Range	(2.2, 4.2)	(3.3, 3.3)	(3, 3.6)	(2.7, 2.7)	(1.8, 3.4)	(2.6, 2.6)	(1.9, 3)	(2.5, 2.5)
White Blood Cells (10^9/L)	n	4	1	4	1	4	1	4	1
	Mean (sd)	5.42 (1.39)	12.5 ()	6.42 (2.19)	11.7 ()	5.5 (1.04)	9.8 ()	5.88 (0.98)	11.1 ()
	Median	5.4	12.5	6.35	11.7	5.6	9.8	5.95	11.1
	IQR	(4.4, 6.45)	(12.5, 12.5)	(4.7, 8.15)	(11.7, 11.7)	(4.7, 6.3)	(9.8, 9.8)	(5.25, 6.5)	(11.1, 11.1)
	Range	(3.8, 7.1)	(12.5, 12.5)	(4, 9)	(11.7, 11.7)	(4.2, 6.6)	(9.8, 9.8)	(4.6, 7)	(11.1, 11.1)

Table 5. Clinical laboratory results over time since registration, visits 3a, 4, 5 and 6

Test	Stat	Visit 3a		Visit 4		Visit 5		Visit 6	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Alanine Transferase (ALT, U/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	22 (4.24)	NaN ()	17.75 (7.41)	27 ()	17.5 (7.14)	30 ()	15.25 (6.65)	NaN ()
	Median	22		18.5	27	20.5	30	15.5	
	IQR	(19, 25)	(, NA)	(13, 22.5)	(27, 27)	(13, 22)	(30, 30)	(10.5, 20)	(, NA)
	Range	(19, 25)	(Inf, -Inf)	(8, 26)	(27, 27)	(7, 22)	(30, 30)	(7, 23)	(Inf, -Inf)
Albumin (g/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	37.5 (0.71)	NaN ()	35.25 (3.59)	43 ()	34.5 (4.65)	40 ()	35.75 (4.27)	NaN ()
	Median	37.5		36.5	43	35.5	40	35.5	
	IQR	(37, 38)	(, NA)	(33, 37.5)	(43, 43)	(31.5, 37.5)	(40, 40)	(32.5, 39)	(, NA)
	Range	(37, 38)	(Inf, -Inf)	(30, 38)	(43, 43)	(28, 39)	(40, 40)	(31, 41)	(Inf, -Inf)
Alkaline Phosphatase (ALP, U/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	76.5 (20.51)	NaN ()	81 (18.49)	124 ()	74.25 (19.38)	127 ()	74.5 (16.2)	NaN ()
	Median	76.5		81.5	124	75	127	76	
	IQR	(62, 91)	(, NA)	(65.5, 96.5)	(124, 124)	(58.5, 90)	(127, 127)	(61, 88)	(, NA)
	Range	(62, 91)	(Inf, -Inf)	(61, 100)	(124, 124)	(52, 95)	(127, 127)	(56, 90)	(Inf, -Inf)
APTT	n	2	0	4	1	3	1	4	0
	Mean (sd)	0.95 (0.07)	NaN ()	0.98 (0.1)	1.1 ()	1.03 (0.12)	1 ()	0.98 (0.1)	NaN ()
	Median	0.95		0.95	1.1	1.1	1	0.95	
	IQR	(0.9, 1)	(, NA)	(0.9, 1.05)	(1.1, 1.1)	(0.9, 1.1)	(1, 1)	(0.9, 1.05)	(, NA)
	Range	(0.9, 1)	(Inf, -Inf)	(0.9, 1.1)	(1.1, 1.1)	(0.9, 1.1)	(1, 1)	(0.9, 1.1)	(Inf, -Inf)
Aspartate Transaminase (AST, U/L)	n	2	0	4	1	4	0	4	0
	Mean (sd)	27 (5.66)	NaN ()	21.25 (7.76)	33 ()	21.75 (8.66)	NaN ()	19.5 (7.85)	NaN ()
	Median	27		22.5	33	23.5		19.5	
	IQR	(23, 31)	(, NA)	(15.5, 27)	(33, 33)	(15.5, 28)	(, NA)	(14, 25)	(, NA)
	Range	(23, 31)	(Inf, -Inf)	(11, 29)	(33, 33)	(10, 30)	(Inf, -Inf)	(10, 29)	(Inf, -Inf)
Basophils (10 ⁹ /L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	0.1 (0)	NaN ()	0.03 (0.05)	0.1 ()	0.03 (0.05)	0.1 ()	0.1 (0.14)	NaN ()
	Median	0.1		0	0.1	0	0.1	0.05	
	IQR	(0.1, 0.1)	(, NA)	(0, 0.05)	(0.1, 0.1)	(0, 0.05)	(0.1, 0.1)	(0, 0.2)	(, NA)
	Range	(0.1, 0.1)	(Inf, -Inf)	(0, 0.1)	(0.1, 0.1)	(0, 0.1)	(0.1, 0.1)	(0, 0.3)	(Inf, -Inf)
Bilirubin (total, umol/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	8.5 (3.54)	NaN ()	7.25 (1.5)	12 ()	7.5 (3.79)	7 ()	6 (2.45)	NaN ()
	Median	8.5		7	12	6	7	6.5	
	IQR	(6, 11)	(, NA)	(6, 8.5)	(12, 12)	(5, 10)	(7, 7)	(4, 8)	(, NA)

Test	Stat	Visit 3a		Visit 4		Visit 5		Visit 6	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
C-Reactive Protein (CRP, mg/L)	Range	(6, 11)	(Inf, -Inf)	(6, 9)	(12, 12)	(5, 13)	(7, 7)	(3, 8)	(Inf, -Inf)
	n	2	0	4	1	4	1	4	0
	Mean (sd)	3 (2.83)	NaN ()	3 (4)	9 ()	2 (1.41)	9 ()	2.5 (2.38)	NaN ()
	Median	3		1	9	1.5	9	1.5	
	IQR	(1, 5)	(, NA)	(1, 5)	(9, 9)	(1, 3)	(9, 9)	(1, 4)	(, NA)
	Range	(1, 5)	(Inf, -Inf)	(1, 9)	(9, 9)	(1, 4)	(9, 9)	(1, 6)	(Inf, -Inf)
Calcium (mmol/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	2.37 (0.01)	NaN ()	2.29 (0.09)	2.48 ()	2.27 (0.12)	2.39 ()	2.27 (0.11)	NaN ()
	Median	2.37		2.33	2.48	2.28	2.39	2.32	
	IQR	(2.36, 2.37)	(, NA)	(2.24, 2.34)	(2.48, 2.48)	(2.18, 2.35)	(2.39, 2.39)	(2.2, 2.34)	(, NA)
	Range	(2.36, 2.37)	(Inf, -Inf)	(2.16, 2.36)	(2.48, 2.48)	(2.11, 2.39)	(2.39, 2.39)	(2.11, 2.34)	(Inf, -Inf)
Creatinine (umol/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	66 (16.97)	NaN ()	64.75 (8.66)	62 ()	63 (14.02)	60 ()	64.5 (12.23)	NaN ()
	Median	66		62.5	62	56.5	60	61	
	IQR	(54, 78)	(, NA)	(59, 70.5)	(62, 62)	(55.5, 70.5)	(60, 60)	(56.5, 72.5)	(, NA)
	Range	(54, 78)	(Inf, -Inf)	(57, 77)	(62, 62)	(55, 84)	(60, 60)	(54, 82)	(Inf, -Inf)
eGFR (mL/min/1.7)	n	2	0	3	1	3	1	3	0
	Mean (sd)	90 (0)	NaN ()	90 (0)	89 ()	89 (1.73)	90 ()	89 (1)	NaN ()
	Median	90		90	89	90	90	89	
	IQR	(90, 90)	(, NA)	(90, 90)	(89, 89)	(87, 90)	(90, 90)	(88, 90)	(, NA)
	Range	(90, 90)	(Inf, -Inf)	(90, 90)	(89, 89)	(87, 90)	(90, 90)	(88, 90)	(Inf, -Inf)
Eosinophils (10^9/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	0.25 (0.21)	NaN ()	0.2 (0.08)	0.1 ()	0.18 (0.05)	0.1 ()	0.2 (0.08)	NaN ()
	Median	0.25		0.2	0.1	0.2	0.1	0.2	
	IQR	(0.1, 0.4)	(, NA)	(0.15, 0.25)	(0.1, 0.1)	(0.15, 0.2)	(0.1, 0.1)	(0.15, 0.25)	(, NA)
	Range	(0.1, 0.4)	(Inf, -Inf)	(0.1, 0.3)	(0.1, 0.1)	(0.1, 0.2)	(0.1, 0.1)	(0.1, 0.3)	(Inf, -Inf)
Haematocrit (L/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	0.39 (0.03)	NaN ()	0.38 (0.03)	0.39 ()	0.38 (0.05)	0.38 ()	0.37 (0.04)	NaN ()
	Median	0.39		0.39	0.39	0.38	0.38	0.37	
	IQR	(0.37, 0.41)	(, NA)	(0.36, 0.41)	(0.39, 0.39)	(0.34, 0.42)	(0.38, 0.38)	(0.34, 0.41)	(, NA)
	Range	(0.37, 0.41)	(Inf, -Inf)	(0.34, 0.41)	(0.39, 0.39)	(0.33, 0.42)	(0.38, 0.38)	(0.34, 0.41)	(Inf, -Inf)
Haemoglobin (g/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	130 (11.31)	NaN ()	128 (13.14)	130 ()	124.5 (18.27)	125 ()	123.75 (16.54)	NaN ()
	Median	130		129.5	130	123.5	125	123	
	IQR	(122, 138)	(, NA)	(117, 139)	(130, 130)	(109, 140)	(125, 125)	(109.5, 138)	(, NA)
	Range	(122, 138)	(Inf, -Inf)	(113, 140)	(130, 130)	(107, 144)	(125, 125)	(109, 140)	(Inf, -Inf)

Test	Stat	Visit 3a		Visit 4		Visit 5		Visit 6	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
INR	n	2	0	4	1	3	1	4	0
	Mean (sd)	0.9 (0)	NaN ()	0.92 (0.05)	1 ()	0.93 (0.06)	1 ()	0.92 (0.05)	NaN ()
	Median	0.9		0.9	1	0.9	1	0.9	
	IQR	(0.9, 0.9)	(, NA)	(0.9, 0.95)	(1, 1)	(0.9, 1)	(1, 1)	(0.9, 0.95)	(, NA)
	Range	(0.9, 0.9)	(Inf, -Inf)	(0.9, 1)	(1, 1)	(0.9, 1)	(1, 1)	(0.9, 1)	(Inf, -Inf)
Lymphocytes (10^9/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	1.3 (0.42)	NaN ()	1.45 (0.54)	2.6 ()	1.23 (0.59)	3.1 ()	1.32 (0.59)	NaN ()
	Median	1.3		1.55	2.6	1.25	3.1	1.45	
	IQR	(1, 1.6)	(, NA)	(1.1, 1.8)	(2.6, 2.6)	(0.8, 1.65)	(3.1, 3.1)	(0.95, 1.7)	(, NA)
	Range	(1, 1.6)	(Inf, -Inf)	(0.7, 2)	(2.6, 2.6)	(0.5, 1.9)	(3.1, 3.1)	(0.5, 1.9)	(Inf, -Inf)
Mean Cell Haemoglobin (pg)	n	2	0	3	1	3	1	3	0
	Mean (sd)	29 (0)	NaN ()	29 (0)	29 ()	28.67 (0.58)	30 ()	28.67 (0.58)	NaN ()
	Median	29		29	29	29	30	29	
	IQR	(29, 29)	(, NA)	(29, 29)	(29, 29)	(28, 29)	(30, 30)	(28, 29)	(, NA)
	Range	(29, 29)	(Inf, -Inf)	(29, 29)	(29, 29)	(28, 29)	(30, 30)	(28, 29)	(Inf, -Inf)
Mean Cell Volume (fl)	n	2	0	3	1	3	1	3	0
	Mean (sd)	86 (0)	NaN ()	86.67 (1.53)	89 ()	87 (2)	89 ()	85.33 (3.06)	NaN ()
	Median	86		87	89	87	89	86	
	IQR	(86, 86)	(, NA)	(85, 88)	(89, 89)	(85, 89)	(89, 89)	(82, 88)	(, NA)
	Range	(86, 86)	(Inf, -Inf)	(85, 88)	(89, 89)	(85, 89)	(89, 89)	(82, 88)	(Inf, -Inf)
Monocytes (10^9/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	0.55 (0.21)	NaN ()	0.58 (0.05)	0.8 ()	0.5 (0.14)	0.7 ()	0.55 (0.13)	NaN ()
	Median	0.55		0.6	0.8	0.55	0.7	0.55	
	IQR	(0.4, 0.7)	(, NA)	(0.55, 0.6)	(0.8, 0.8)	(0.4, 0.6)	(0.7, 0.7)	(0.45, 0.65)	(, NA)
	Range	(0.4, 0.7)	(Inf, -Inf)	(0.5, 0.6)	(0.8, 0.8)	(0.3, 0.6)	(0.7, 0.7)	(0.4, 0.7)	(Inf, -Inf)
Neutrophils (10^9/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	3.5 (1.27)	NaN ()	3.62 (0.68)	7.6 ()	3.78 (1.02)	5.6 ()	3.57 (0.7)	NaN ()
	Median	3.5		3.45	7.6	3.85	5.6	3.35	
	IQR	(2.6, 4.4)	(, NA)	(3.2, 4.05)	(7.6, 7.6)	(3, 4.55)	(5.6, 5.6)	(3.15, 4)	(, NA)
	Range	(2.6, 4.4)	(Inf, -Inf)	(3, 4.6)	(7.6, 7.6)	(2.5, 4.9)	(5.6, 5.6)	(3, 4.6)	(Inf, -Inf)
Platelets (10^9/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	309 (11.31)	NaN ()	318.25 (45.78)	304 ()	300 (35)	327 ()	302.5 (19.47)	NaN ()
	Median	309		337.5	304	297.5	327	297.5	
	IQR	(301, 317)	(, NA)	(293, 343.5)	(304, 304)	(270, 330)	(327, 327)	(289.5, 315.5)	(, NA)
	Range	(301, 317)	(Inf, -Inf)	(250, 348)	(304, 304)	(269, 336)	(327, 327)	(285, 330)	(Inf, -Inf)
Potassium	n	2	0	4	1	4	1	4	0

Test	Stat	Visit 3a		Visit 4		Visit 5		Visit 6	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
(mmol/L)	Mean (sd)	4.55 (0.35)	NaN ()	4.4 (0.37)	4.2 ()	4.2 (0.35)	4.4 ()	4.22 (0.35)	NaN ()
	Median	4.55		4.35	4.2	4.1	4.4	4.25	
	IQR	(4.3, 4.8)	(, NA)	(4.15, 4.65)	(4.2, 4.2)	(4, 4.4)	(4.4, 4.4)	(3.95, 4.5)	(, NA)
	Range	(4.3, 4.8)	(Inf, -Inf)	(4, 4.9)	(4.2, 4.2)	(3.9, 4.7)	(4.4, 4.4)	(3.8, 4.6)	(Inf, -Inf)
Red Blood Cells (10^12/L)	n	2	0	4	1	4	1	4	0
	Mean (sd)	4.46 (0.36)	NaN ()	4.51 (0.28)	4.43 ()	4.42 (0.51)	4.21 ()	4.43 (0.48)	NaN ()
	Median	4.46		4.54	4.43	4.42	4.21	4.52	
	IQR	(4.21, 4.72)	(, NA)	(4.28, 4.74)	(4.43, 4.43)	(4.03, 4.82)	(4.21, 4.21)	(4.06, 4.81)	(, NA)
Sodium (mmol/L)	Range	(4.21, 4.72)	(Inf, -Inf)	(4.17, 4.78)	(4.43, 4.43)	(3.84, 5.01)	(4.21, 4.21)	(3.82, 4.88)	(Inf, -Inf)
	n	2	0	4	1	4	1	4	0
	Mean (sd)	139.5 (2.12)	NaN ()	138 (1.41)	135 ()	138 (0.82)	142 ()	139.5 (0.58)	NaN ()
	Median	139.5		138.5	135	138	142	139.5	
Total Protein (g/L)	IQR	(138, 141)	(, NA)	(137, 139)	(135, 135)	(137.5, 138.5)	(142, 142)	(139, 140)	(, NA)
	Range	(138, 141)	(Inf, -Inf)	(136, 139)	(135, 135)	(137, 139)	(142, 142)	(139, 140)	(Inf, -Inf)
	n	2	0	4	1	4	1	4	0
	Mean (sd)	73.5 (0.71)	NaN ()	67.75 (6.34)	74 ()	66.25 (8.02)	71 ()	66.25 (5.85)	NaN ()
Urea (mmol/L)	Median	73.5		69	74	68	71	66.5	
	IQR	(73, 74)	(, NA)	(63.5, 72)	(74, 74)	(61.5, 71)	(71, 71)	(62, 70.5)	(, NA)
	Range	(73, 74)	(Inf, -Inf)	(59, 74)	(74, 74)	(55, 74)	(71, 71)	(59, 73)	(Inf, -Inf)
	n	2	0	4	1	4	1	4	0
White Blood Cells (10^9/L)	Mean (sd)	2.9 (0.28)	NaN ()	3.3 (0.73)	3.7 ()	2.95 (0.85)	2.9 ()	3 (0.61)	NaN ()
	Median	2.9		3.15	3.7	3	2.9	3.1	
	IQR	(2.7, 3.1)	(, NA)	(2.8, 3.8)	(3.7, 3.7)	(2.3, 3.6)	(2.9, 2.9)	(2.55, 3.45)	(, NA)
	Range	(2.7, 3.1)	(Inf, -Inf)	(2.6, 4.3)	(3.7, 3.7)	(1.9, 3.9)	(2.9, 2.9)	(2.2, 3.6)	(Inf, -Inf)

Table 6. Clinical laboratory results over time since registration, visits 7, 8, 9, 10 and Unscheduled visits

Test	Stat	Visit 7		Visit 8		Visit 9		Visit 10		Unscheduled Visit	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Alanine Transferase (ALT, U/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	14 (6.27)	28 ()	23 (8.98)	28 ()	22.5 (10.61)	25 ()	35 ()	26 ()	14 ()	
	Median	12.5	28	19.5	28	22.5	25	35	26	14	
	IQR	(9, 19)	(28, 28)	(17, 29)	(28, 28)	(15, 30)	(25, 25)	(35, 35)	(26, 26)	(14, 14)	
	Range	(9, 22)	(28, 28)	(17, 36)	(28, 28)	(15, 30)	(25, 25)	(35, 35)	(26, 26)	(14, 14)	
Albumin (g/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	34.25 (4.92)	39 ()	36.25 (7.23)	39 ()	38.5 (3.54)	36 ()	40 ()	35 ()	34 ()	
	Median	34.5	39	38	39	38.5	36	40	35	34	
	IQR	(31, 37.5)	(39, 39)	(32, 40.5)	(39, 39)	(36, 41)	(36, 36)	(40, 40)	(35, 35)	(34, 34)	
	Range	(28, 40)	(39, 39)	(26, 43)	(39, 39)	(36, 41)	(36, 36)	(40, 40)	(35, 35)	(34, 34)	
Alkaline Phosphatase (ALP, U/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	74.5 (22.29)	115 ()	85 (22.52)	114 ()	93.5 (4.95)	123 ()	95 ()	113 ()	90 ()	
	Median	74	115	86.5	114	93.5	123	95	113	90	
	IQR	(56, 93)	(115, 115)	(66.5, 103.5)	(114, 114)	(90, 97)	(123, 123)	(95, 95)	(113, 113)	(90, 90)	
	Range	(51, 99)	(115, 115)	(59, 108)	(114, 114)	(90, 97)	(123, 123)	(95, 95)	(113, 113)	(90, 90)	
APTT	n	4	1	4	1	1	1	1	1	1	
	Mean (sd)	0.92 (0.1)	1 ()	0.98 (0.05)	1.1 ()	0.8 ()	1.1 ()	1 ()	1 ()	0.9 ()	
	Median	0.95	1	1	1.1	0.8	1.1	1	1	0.9	
	IQR	(0.85, 1)	(1, 1)	(0.95, 1)	(1.1, 1.1)	(0.8, 0.8)	(1.1, 1.1)	(1, 1)	(1, 1)	(0.9, 0.9)	
	Range	(0.8, 1)	(1, 1)	(0.9, 1)	(1.1, 1.1)	(0.8, 0.8)	(1.1, 1.1)	(1, 1)	(1, 1)	(0.9, 0.9)	
Aspartate Transaminase (AST, U/L)	n	4	1	4	0	2	1	1	1	1	
	Mean (sd)	19 (8.68)	39 ()	24 (12.03)	NaN ()	27.5 (12.02)	33 ()	36 ()	46 ()	18 ()	
	Median	19.5	39	22.5		27.5	33	36	46	18	
	IQR	(13, 25)	(39, 39)	(16, 32)	(, NA)	(19, 36)	(33, 33)	(36, 36)	(46, 46)	(18, 18)	
	Range	(8, 29)	(39, 39)	(11, 40)	(Inf, -Inf)	(19, 36)	(33, 33)	(36, 36)	(46, 46)	(18, 18)	
Basophils (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	0.04 (0.04)	0.1 ()	0.04 (0.05)	0.1 ()	0.06 (0.08)	0.1 ()	0.04 ()	0.1 ()	0.1 ()	
	Median	0.03	0.1	0.02	0.1	0.06	0.1	0.04	0.1	0.1	
	IQR	(0.01, 0.07)	(0.1, 0.1)	(0, 0.06)	(0.1, 0.1)	(0, 0.11)	(0.1, 0.1)	(0.04, 0.04)	(0.1, 0.1)	(0.1, 0.1)	
	Range	(0, 0.1)	(0.1, 0.1)	(0, 0.1)	(0.1, 0.1)	(0, 0.11)	(0.1, 0.1)	(0.04, 0.04)	(0.1, 0.1)	(0.1, 0.1)	
Bilirubin (total, umol/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	6.75 (3.1)	10 ()	10 (4.97)	15 ()	9 (2.83)	9 ()	15 ()	11 ()	5 ()	
	Median	6	10	10	15	9	9	15	11	5	
	IQR	(4.5, 9)	(10, 10)	(6.5, 13.5)	(15, 15)	(7, 11)	(9, 9)	(15, 15)	(11, 11)	(5, 5)	

Test	Stat	Visit 7		Visit 8		Visit 9		Visit 10		Unscheduled Visit	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
	Range	(4, 11)	(10, 10)	(4, 16)	(15, 15)	(7, 11)	(9, 9)	(15, 15)	(11, 11)	(5, 5)	
C-Reactive Protein (CRP, mg/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	5 (8)	11 ()	10 (17.34)	6 ()	1 (0)	12 ()	1 ()	10 ()	1 ()	
	Median	1	11	1.5	6	1	12	1	10	1	
	IQR	(1, 9)	(11, 11)	(1, 19)	(6, 6)	(1, 1)	(12, 12)	(1, 1)	(10, 10)	(1, 1)	
	Range	(1, 17)	(11, 11)	(1, 36)	(6, 6)	(1, 1)	(12, 12)	(1, 1)	(10, 10)	(1, 1)	
Calcium (mmol/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	2.21 (0.08)	2.58 ()	2.28 (0.15)	2.43 ()	2.38 (0.03)	2.45 ()	2.33 ()	2.28 ()	2.34 ()	
	Median	2.24	2.58	2.31	2.43	2.38	2.45	2.33	2.28	2.34	
	IQR	(2.16, 2.26)	(2.58, 2.58)	(2.17, 2.38)	(2.43, 2.43)	(2.36, 2.4)	(2.45, 2.45)	(2.33, 2.33)	(2.28, 2.28)	(2.34, 2.34)	
	Range	(2.1, 2.27)	(2.58, 2.58)	(2.07, 2.41)	(2.43, 2.43)	(2.36, 2.4)	(2.45, 2.45)	(2.33, 2.33)	(2.28, 2.28)	(2.34, 2.34)	
Creatinine (umol/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	66 (15.68)	59 ()	70.75 (17.52)	64 ()	77.5 (20.51)	64 ()	99 ()	57 ()	63 ()	
	Median	60.5	59	68	64	77.5	64	99	57	63	
	IQR	(56.5, 75.5)	(59, 59)	(58, 83.5)	(64, 64)	(63, 92)	(64, 64)	(99, 99)	(57, 57)	(63, 63)	
	Range	(54, 89)	(59, 59)	(53, 94)	(64, 64)	(63, 92)	(64, 64)	(99, 99)	(57, 57)	(63, 63)	
eGFR (mL/min/1.7)	n	3	1	4	1	2	1	1	1	1	
	Mean (sd)	86.67 (4.93)	90 ()	85 (6.22)	86 ()	83 (7.07)	86 ()	72 ()	90 ()	88 ()	
	Median	89	90	87	86	83	86	72	90	88	
	IQR	(81, 90)	(90, 90)	(81, 89)	(86, 86)	(78, 88)	(86, 86)	(72, 72)	(90, 90)	(88, 88)	
	Range	(81, 90)	(90, 90)	(76, 90)	(86, 86)	(78, 88)	(86, 86)	(72, 72)	(90, 90)	(88, 88)	
Eosinophils (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	0.15 (0.06)	0.2 ()	0.17 (0.1)	0.1 ()	0.4 (0.28)	0.2 ()	0.2 ()	0.1 ()	0.2 ()	
	Median	0.15	0.2	0.15	0.1	0.4	0.2	0.2	0.1	0.2	
	IQR	(0.1, 0.2)	(0.2, 0.2)	(0.1, 0.25)	(0.1, 0.1)	(0.2, 0.6)	(0.2, 0.2)	(0.2, 0.2)	(0.1, 0.1)	(0.2, 0.2)	
	Range	(0.1, 0.2)	(0.2, 0.2)	(0.1, 0.3)	(0.1, 0.1)	(0.2, 0.6)	(0.2, 0.2)	(0.2, 0.2)	(0.1, 0.1)	(0.2, 0.2)	
Haematocrit (L/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	0.39 (0.04)	0.39 ()	0.38 (0.06)	0.39 ()	0.42 (0.03)	0.37 ()	0.45 ()	0.36 ()	0.4 ()	
	Median	0.38	0.39	0.38	0.39	0.42	0.37	0.45	0.36	0.4	
	IQR	(0.36, 0.42)	(0.39, 0.39)	(0.32, 0.43)	(0.39, 0.39)	(0.4, 0.44)	(0.37, 0.37)	(0.45, 0.45)	(0.36, 0.36)	(0.4, 0.4)	
	Range	(0.34, 0.44)	(0.39, 0.39)	(0.3, 0.45)	(0.39, 0.39)	(0.4, 0.44)	(0.37, 0.37)	(0.45, 0.45)	(0.36, 0.36)	(0.4, 0.4)	
Haemoglobin (g/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	123 (19.65)	131 ()	122.25 (26.17)	127 ()	140.5 (10.61)	123 ()	142 ()	118 ()	140 ()	
	Median	123.5	131	123.5	127	140.5	123	142	118	140	
	IQR	(107.5, 138.5)	(131, 131)	(100.5, 144)	(127, 127)	(133, 148)	(123, 123)	(142, 142)	(118, 118)	(140, 140)	
	Range	(100, 145)	(131, 131)	(93, 149)	(127, 127)	(133, 148)	(123, 123)	(142, 142)	(118, 118)	(140, 140)	

Test	Stat	Visit 7		Visit 8		Visit 9		Visit 10		Unscheduled Visit	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
INR	n	4	1	4	1	1	1	1	1	1	
	Mean (sd)	0.92 (0.1)	1 ()	0.95 (0.06)	1 ()	0.9 ()	0.9 ()	0.9 ()	1 ()	0.9 ()	
	Median	0.95	1	0.95	1	0.9	0.9	0.9	1	0.9	
	IQR	(0.85, 1)	(1, 1)	(0.9, 1)	(1, 1)	(0.9, 0.9)	(0.9, 0.9)	(0.9, 0.9)	(1, 1)	(0.9, 0.9)	
	Range	(0.8, 1)	(1, 1)	(0.9, 1)	(1, 1)	(0.9, 0.9)	(0.9, 0.9)	(0.9, 0.9)	(1, 1)	(0.9, 0.9)	
Lymphocytes (10^9/L)	n	3	1	4	1	2	1	1	1	1	
	Mean (sd)	1.37 (0.06)	2.3 ()	1.32 (0.66)	2.4 ()	2.05 (0.21)	2.8 ()	1.7 ()	2.3 ()	1.9 ()	
	Median	1.4	2.3	1.45	2.4	2.05	2.8	1.7	2.3	1.9	
	IQR	(1.3, 1.4)	(2.3, 2.3)	(0.8, 1.85)	(2.4, 2.4)	(1.9, 2.2)	(2.8, 2.8)	(1.7, 1.7)	(2.3, 2.3)	(1.9, 1.9)	
	Range	(1.3, 1.4)	(2.3, 2.3)	(0.5, 1.9)	(2.4, 2.4)	(1.9, 2.2)	(2.8, 2.8)	(1.7, 1.7)	(2.3, 2.3)	(1.9, 1.9)	
Mean Cell Haemoglobin (pg)	n	3	1	4	1	2	1	1	1	1	
	Mean (sd)	28.67 (0.58)	29 ()	27.25 (2.22)	28 ()	28 (1.41)	28 ()	28 ()	33 ()	29 ()	
	Median	29	29	28	28	28	28	28	33	29	
	IQR	(28, 29)	(29, 29)	(26, 28.5)	(28, 28)	(27, 29)	(28, 28)	(28, 28)	(33, 33)	(29, 29)	
	Range	(28, 29)	(29, 29)	(24, 29)	(28, 28)	(27, 29)	(28, 28)	(28, 28)	(33, 33)	(29, 29)	
Mean Cell Volume (fl)	n	3	1	4	1	2	1	1	1	1	
	Mean (sd)	87.33 (5.13)	87 ()	83.75 (5.56)	87 ()	84 (5.66)	85 ()	91 ()	86 ()	82 ()	
	Median	86	87	84	87	84	85	91	86	82	
	IQR	(83, 93)	(87, 87)	(79.5, 88)	(87, 87)	(80, 88)	(85, 85)	(91, 91)	(86, 86)	(82, 82)	
	Range	(83, 93)	(87, 87)	(77, 90)	(87, 87)	(80, 88)	(85, 85)	(91, 91)	(86, 86)	(82, 82)	
Monocytes (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	0.5 (0.08)	0.7 ()	0.4 (0.08)	0.5 ()	0.55 (0.07)	0.7 ()	0.6 ()	0.5 ()	0.7 ()	
	Median	0.5	0.7	0.4	0.5	0.55	0.7	0.6	0.5	0.7	
	IQR	(0.45, 0.55)	(0.7, 0.7)	(0.35, 0.45)	(0.5, 0.5)	(0.5, 0.6)	(0.7, 0.7)	(0.6, 0.6)	(0.5, 0.5)	(0.7, 0.7)	
	Range	(0.4, 0.6)	(0.7, 0.7)	(0.3, 0.5)	(0.5, 0.5)	(0.5, 0.6)	(0.7, 0.7)	(0.6, 0.6)	(0.5, 0.5)	(0.7, 0.7)	
Neutrophils (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	3.83 (0.17)	4.6 ()	3.32 (1.1)	5.4 ()	4.5 (0.14)	5.8 ()	4.2 ()	6.3 ()	3.4 ()	
	Median	3.85	4.6	3.75	5.4	4.5	5.8	4.2	6.3	3.4	
	IQR	(3.7, 3.95)	(4.6, 4.6)	(2.7, 3.95)	(5.4, 5.4)	(4.4, 4.6)	(5.8, 5.8)	(4.2, 4.2)	(6.3, 6.3)	(3.4, 3.4)	
	Range	(3.6, 4)	(4.6, 4.6)	(1.7, 4.1)	(5.4, 5.4)	(4.4, 4.6)	(5.8, 5.8)	(4.2, 4.2)	(6.3, 6.3)	(3.4, 3.4)	
Platelets (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	326.5 (48.09)	286 ()	337 (23.25)	335 ()	332 (56.57)	326 ()	339 ()	247 ()	285 ()	
	Median	338.5	286	340	335	332	326	339	247	285	
	IQR	(292, 361)	(286, 286)	(319.5, 354.5)	(335, 335)	(292, 372)	(326, 326)	(339, 339)	(247, 247)	(285, 285)	
	Range	(260, 369)	(286, 286)	(307, 361)	(335, 335)	(292, 372)	(326, 326)	(339, 339)	(247, 247)	(285, 285)	
Potassium	n	4	1	4	0	2	1	1	1	1	

Test	Stat	Visit 7		Visit 8		Visit 9		Visit 10		Unscheduled Visit	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
(mmol/L)	Mean (sd)	4.2 (0.2)	4.3 ()	3.9 (0.28)	NaN ()	4.35 (0.21)	4.3 ()	4.6 ()	3.9 ()	4.4 ()	
	Median	4.3	4.3	4		4.35	4.3	4.6	3.9	4.4	
	IQR	(4.1, 4.3)	(4.3, 4.3)	(3.7, 4.1)	(, NA)	(4.2, 4.5)	(4.3, 4.3)	(4.6, 4.6)	(3.9, 3.9)	(4.4, 4.4)	
	Range	(3.9, 4.3)	(4.3, 4.3)	(3.5, 4.1)	(Inf, -Inf)	(4.2, 4.5)	(4.3, 4.3)	(4.6, 4.6)	(3.9, 3.9)	(4.4, 4.4)	
Red Blood Cells (10^12/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	4.48 (0.49)	4.5 ()	4.47 (0.71)	4.49 ()	5 (0.06)	4.36 ()	5 ()	4.14 ()	4.88 ()	
	Median	4.37	4.5	4.4	4.49	5	4.36	5	4.14	4.88	
	IQR	(4.09, 4.87)	(4.5, 4.5)	(3.87, 5.08)	(4.49, 4.49)	(4.95, 5.04)	(4.36, 4.36)	(5, 5)	(4.14, 4.14)	(4.88, 4.88)	
	Range	(4.08, 5.1)	(4.5, 4.5)	(3.86, 5.21)	(4.49, 4.49)	(4.95, 5.04)	(4.36, 4.36)	(5, 5)	(4.14, 4.14)	(4.88, 4.88)	
Sodium (mmol/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	139.5 (0.58)	140 ()	140 (2.83)	139 ()	142.5 (0.71)	140 ()	142 ()	137 ()	140 ()	
	Median	139.5	140	139	139	142.5	140	142	137	140	
	IQR	(139, 140)	(140, 140)	(138, 142)	(139, 139)	(142, 143)	(140, 140)	(142, 142)	(137, 137)	(140, 140)	
	Range	(139, 140)	(140, 140)	(138, 144)	(139, 139)	(142, 143)	(140, 140)	(142, 142)	(137, 137)	(140, 140)	
Total Protein (g/L)	n	4	1	4	0	2	1	1	1	1	
	Mean (sd)	65 (7.79)	81 ()	71.25 (10.34)	NaN ()	72 (5.66)	72 ()	75 ()	70 ()	65 ()	
	Median	64.5	81	70		72	72	75	70	65	
	IQR	(60, 70)	(81, 81)	(64.5, 78)	(, NA)	(68, 76)	(72, 72)	(75, 75)	(70, 70)	(65, 65)	
	Range	(56, 75)	(81, 81)	(60, 85)	(Inf, -Inf)	(68, 76)	(72, 72)	(75, 75)	(70, 70)	(65, 65)	
Urea (mmol/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	2.9 (0.47)	3.5 ()	2.92 (0.87)	2.5 ()	2.8 (0.42)	3.7 ()	4.7 ()	3.4 ()	2.9 ()	
	Median	3.1	3.5	3.15	2.5	2.8	3.7	4.7	3.4	2.9	
	IQR	(2.65, 3.15)	(3.5, 3.5)	(2.35, 3.5)	(2.5, 2.5)	(2.5, 3.1)	(3.7, 3.7)	(4.7, 4.7)	(3.4, 3.4)	(2.9, 2.9)	
	Range	(2.2, 3.2)	(3.5, 3.5)	(1.7, 3.7)	(2.5, 2.5)	(2.5, 3.1)	(3.7, 3.7)	(4.7, 4.7)	(3.4, 3.4)	(2.9, 2.9)	
White Blood Cells (10^9/L)	n	4	1	4	1	2	1	1	1	1	
	Mean (sd)	5.7 (0.43)	7.8 ()	5.28 (1.8)	8.4 ()	7.6 (0.85)	9.5 ()	6.7 ()	9.3 ()	6.2 ()	
	Median	5.8	7.8	5.9	8.4	7.6	9.5	6.7	9.3	6.2	
	IQR	(5.4, 6)	(7.8, 7.8)	(4.05, 6.5)	(8.4, 8.4)	(7, 8.2)	(9.5, 9.5)	(6.7, 6.7)	(9.3, 9.3)	(6.2, 6.2)	
	Range	(5.1, 6.1)	(7.8, 7.8)	(2.7, 6.6)	(8.4, 8.4)	(7, 8.2)	(9.5, 9.5)	(6.7, 6.7)	(9.3, 9.3)	(6.2, 6.2)	

d) Electrocardiograms (ECGs)

Table 7. Summary of ECG results

Test	Stat	Visit 1		Visit 3 (pre-dose)		Visit 3 (60 mins post dose)		Visit 5		Visit 10	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Heart Rate (beats per minute)	n	4	1	4	1	4	1	4	1	1	1
	Mean (sd)	72.5 (9.71)	72 (NA)	73.5 (2.08)	90 (NA)	78.75 (3.86)	85 (NA)	75.75 (9.54)	80 (NA)	68 (NA)	95 (NA)
	Median	71	72	73.5	90	80.5	85	76	80	68	95
	IQR	(65, 80)	(72, 72)	(72, 75)	(90, 90)	(76.5, 81)	(85, 85)	(67.5, 84)	(80, 80)	(68, 68)	(95, 95)
	Range	(63, 85)	(72, 72)	(71, 76)	(90, 90)	(73, 81)	(85, 85)	(67, 84)	(80, 80)	(68, 68)	(95, 95)
PR (ms)	n	4	1	4	1	4	1	4	1	1	1
	Mean (sd)	138 (17.83)	128 (NA)	141.25 (17.52)	120 (NA)	135.5 (27.23)	160 (NA)	131 (17.53)	115 (NA)	149 (NA)	123 (NA)
	Median	135.5	128	144	120	144.5	160	138.5	115	149	123
	IQR	(126.5, 149.5)	(128, 128)	(128.5, 154)	(120, 120)	(118, 153)	(160, 160)	(120.5, 141.5)	(115, 115)	(149, 149)	(123, 123)
	Range	(119, 162)	(128, 128)	(118, 159)	(120, 120)	(96, 157)	(160, 160)	(105, 142)	(115, 115)	(149, 149)	(123, 123)
QRS Duration (ms)	n	4	1	4	1	4	1	4	1	1	1
	Mean (sd)	76.25 (4.92)	94 (NA)	80 (4.55)	92 (NA)	75.5 (7.05)	120 (NA)	74.25 (6.6)	94 (NA)	79 (NA)	93 (NA)
	Median	76	94	79	92	76.5	120	73.5	94	79	93
	IQR	(72, 80.5)	(94, 94)	(76.5, 83.5)	(92, 92)	(71, 80)	(120, 120)	(70, 78.5)	(94, 94)	(79, 79)	(93, 93)
	Range	(72, 81)	(94, 94)	(76, 86)	(92, 92)	(66, 83)	(120, 120)	(67, 83)	(94, 94)	(79, 79)	(93, 93)
QT (ms)	n	4	1	4	1	4	1	4	1	1	1
	Mean (sd)	364.25 (19.36)	382 (NA)	364.25 (15.88)	356 (NA)	362 (16.57)	280 (NA)	359.5 (19.23)	365 (NA)	405 (NA)	367 (NA)
	Median	362.5	382	360	356	357	280	352	365	405	367
	IQR	(348, 380.5)	(382, 382)	(352.5, 376)	(356, 356)	(352, 372)	(280, 280)	(348.5, 370.5)	(365, 365)	(405, 405)	(367, 367)
	Range	(346, 386)	(382, 382)	(351, 386)	(356, 356)	(348, 386)	(280, 280)	(346, 388)	(365, 365)	(405, 405)	(367, 367)
QTc (ms)	n	4	1	4	1	4	1	4	1	1	1
	Mean (sd)	388.25 (8.92)	406 (NA)	390.25 (14.43)	404 (NA)	396 (11.22)	330 (NA)	388.5 (14.93)	401 (NA)	421 (NA)	420 (NA)
	Median	392	406	386	404	394.5	330	390.5	401	421	420
	IQR	(383, 393.5)	(406, 406)	(381, 399.5)	(404, 404)	(388.5, 403.5)	(330, 330)	(377.5, 399.5)	(401, 401)	(421, 421)	(420, 420)
	Range	(375, 394)	(406, 406)	(378, 411)	(404, 404)	(384, 411)	(330, 330)	(369, 404)	(401, 401)	(421, 421)	(420, 420)

e) Vital signs

Table 8. Summary of vital sign results, visits 1, 2, 3 pre-dose, and 3 during infusion 30 and 60 minutes

Stat		Visit 1		Visit 2		Visit 3 (pre-dose)		Visit 3 (during infusion, 30 mins)		Visit 3 (during infusion, 60 mins)	
		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
		n	n	n	n	n	n	n	n	n	n
Body Temperature (Celcius)	n	4	1	3	1	4	1	4	1	4	1
	Mean (sd)	36.4 (0.47)	36 (NA)	35.77 (0.47)	36.8 (NA)	36.1 (0.16)	37.2 (NA)	36.45 (0.19)	37.2 (NA)	36.47 (0.35)	37.2 (NA)
	Median	36.35	36	35.6	36.8	36.1	37.2	36.5	37.2	36.3	37.2
	IQR	(36.05, 36.75)	(36, 36)	(35.4, 36.3)	(36.8, 36.8)	(36, 36.2)	(37.2, 37.2)	(36.3, 36.6)	(37.2, 37.2)	(36.3, 36.65)	(37.2, 37.2)
	Range	(35.9, 37)	(36, 36)	(35.4, 36.3)	(36.8, 36.8)	(35.9, 36.3)	(37.2, 37.2)	(36.2, 36.6)	(37.2, 37.2)	(36.3, 37)	(37.2, 37.2)
Diastolic Blood Pressure (mmHg)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	71.25 (10.4)	70 (NA)	76.5 (11.79)	90 (NA)	71.75 (11.87)	72 (NA)	75.75 (8.81)	74 (NA)	68.75 (10.37)	76 (NA)
	Median	68	70	76	90	67.5	72	75	74	65	76
	IQR	(64, 78.5)	(70, 70)	(66.5, 86.5)	(90, 90)	(64, 79.5)	(72, 72)	(68.5, 83)	(74, 74)	(62.5, 75)	(76, 76)
	Range	(63, 86)	(70, 70)	(65, 89)	(90, 90)	(63, 89)	(72, 72)	(67, 86)	(74, 74)	(61, 84)	(76, 76)
Heart Rate (beats per minute)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	73.75 (9.18)	75 (NA)	81.75 (5.68)	96 (NA)	79 (6.27)	89 (NA)	81.25 (5.74)	92 (NA)	77.25 (3.2)	87 (NA)
	Median	74	75	79.5	96	80.5	89	81.5	92	76	87
	IQR	(66, 81.5)	(75, 75)	(78, 85.5)	(96, 96)	(74, 84)	(89, 89)	(77.5, 85)	(92, 92)	(75.5, 79)	(87, 87)
	Range	(64, 83)	(75, 75)	(78, 90)	(96, 96)	(71, 84)	(89, 89)	(74, 88)	(92, 92)	(75, 82)	(87, 87)
Respiratory Rate (breaths per minute)	n	3	1	4	1	4	1	4	1	4	1
	Mean (sd)	15.33 (1.15)	14 (NA)	17.25 (1.5)	13 (NA)	16.25 (0.5)	17 (NA)	16 (3.16)	14 (NA)	16.75 (0.96)	13 (NA)
	Median	16	14	18	13	16	17	16.5	14	16.5	13
	IQR	(14, 16)	(14, 14)	(16.5, 18)	(13, 13)	(16, 16.5)	(17, 17)	(13.5, 18.5)	(14, 14)	(16, 17.5)	(13, 13)
	Range	(14, 16)	(14, 14)	(15, 18)	(13, 13)	(16, 17)	(17, 17)	(12, 19)	(14, 14)	(16, 18)	(13, 13)
Systolic Blood Pressure (mmHg)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	111 (8.6)	122 (NA)	119.5 (15)	137 (NA)	112.25 (9.6)	122 (NA)	111.75 (7.72)	113 (NA)	105.25 (9.39)	112 (NA)
	Median	110	122	117	137	109.5	122	111	113	102	112
	IQR	(104.5, 117.5)	(122, 122)	(110, 129)	(137, 137)	(106, 118.5)	(122, 122)	(105.5, 118)	(113, 113)	(99.5, 111)	(112, 112)
	Range	(102, 122)	(122, 122)	(104, 140)	(137, 137)	(104, 126)	(122, 122)	(104, 121)	(113, 113)	(98, 119)	(112, 112)
Weight (kg)	n	0	0	4	1	0	0	0	0	0	0
	Mean (sd)	NaN (NA)	NaN (NA)	58.6 (16.87)	78.2 (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)
	Median	NA	NA	52.95	78.2	NA	NA	NA	NA	NA	NA
	IQR	(NA, NA)	(NA, NA)	(49, 68.2)	(78.2, 78.2)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
	Range	(Inf, -Inf)	(Inf, -Inf)	(45.2, 83.3)	(78.2, 78.2)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)

Table 9. Summary of vital sign results, visit 3: 30, 60, 90, 120 and 150 minutes post-infusion

		Visit 3 (30 mins post-infusion)		Visit 3 (60 mins post-infusion)		Visit 3 (90 mins post-infusion)		Visit 3 (120 mins post-infusion)		Visit 3 (150 mins post-infusion)	
Stat		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Body Temperature (Celsius)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	36.5 (0.23)	37.3 (NA)	36.27 (0.1)	37.1 (NA)	36.48 (0.32)	37.2 (NA)	36.57 (0.26)	36.9 (NA)	36.77 (0.17)	37 (NA)
	Median	36.5	37.3	36.25	37.1	36.45	37.2	36.6	36.9	36.75	37
	IQR	(36.3, 36.7)	(37.3, 37.3)	(36.2, 36.35)	(37.1, 37.1)	(36.2, 36.75)	(37.2, 37.2)	(36.35, 36.8)	(36.9, 36.9)	(36.65, 36.9)	(37, 37)
	Range	(36.3, 36.7)	(37.3, 37.3)	(36.2, 36.4)	(37.1, 37.1)	(36.2, 36.8)	(37.2, 37.2)	(36.3, 36.8)	(36.9, 36.9)	(36.6, 37)	(37, 37)
Diastolic Blood Pressure (mmHg)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	72.25 (9.54)	80 (NA)	67.75 (14.01)	72 (NA)	70 (11.17)	76 (NA)	72.25 (7.37)	80 (NA)	73 (10)	79 (NA)
	Median	70	80	63	72	67	76	72	80	72	79
	IQR	(65, 79.5)	(80, 80)	(58.5, 77)	(72, 72)	(63.5, 76.5)	(76, 76)	(66, 78.5)	(80, 80)	(66, 80)	(79, 79)
	Range	(64, 85)	(80, 80)	(57, 88)	(72, 72)	(60, 86)	(76, 76)	(65, 80)	(80, 80)	(62, 86)	(79, 79)
Heart Rate (beats per minute)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	82.5 (2.08)	101 (NA)	83 (2.71)	91 (NA)	85.25 (4.99)	95 (NA)	88.5 (0.58)	89 (NA)	84.5 (5.74)	87 (NA)
	Median	82.5	101	82	91	84	95	88.5	89	83	87
	IQR	(81, 84)	(101, 101)	(81.5, 84.5)	(91, 91)	(81.5, 89)	(95, 95)	(88, 89)	(89, 89)	(80, 89)	(87, 87)
	Range	(80, 85)	(101, 101)	(81, 87)	(91, 91)	(81, 92)	(95, 95)	(88, 89)	(89, 89)	(80, 92)	(87, 87)
Respiratory Rate (breaths per minute)	n	4	1	4	1	4	1	4	1	4	0
	Mean (sd)	15.75 (2.63)	15 (NA)	17 (0.82)	16 (NA)	16.5 (1)	15 (NA)	16.5 (2.08)	15 (NA)	16.5 (1)	NaN (NA)
	Median	16.5	15	17	16	16	15	16.5	15	16	NA
	IQR	(14, 17.5)	(15, 15)	(16.5, 17.5)	(16, 16)	(16, 17)	(15, 15)	(15, 18)	(15, 15)	(16, 17)	(NA, NA)
	Range	(12, 18)	(15, 15)	(16, 18)	(16, 16)	(16, 18)	(15, 15)	(14, 19)	(15, 15)	(16, 18)	(Inf, -Inf)
Systolic Blood Pressure (mmHg)	n	4	1	4	1	4	1	4	1	4	1
	Mean (sd)	111.5 (11.68)	121 (NA)	109.25 (8.66)	112 (NA)	109.75 (13.89)	112 (NA)	108.25 (9.14)	127 (NA)	108 (14.65)	125 (NA)
	Median	111.5	121	110	112	106.5	112	110	127	103	125
	IQR	(101.5, 121.5)	(121, 121)	(103.5, 115)	(112, 112)	(100, 119.5)	(112, 112)	(101.5, 115)	(127, 127)	(98, 118)	(125, 125)
	Range	(100, 123)	(121, 121)	(98, 119)	(112, 112)	(97, 129)	(112, 112)	(96, 117)	(127, 127)	(97, 129)	(125, 125)
Weight (kg)	n	0	0	0	0	0	0	0	0	0	0
	Mean (sd)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)
	Median	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	IQR	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
	Range	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)

Table 10. Summary of vital sign results, visits 3 (180 minutes post infusion), 3a-6

		Visit 3 (180 mins post dose)		Visit 3a		Visit 4		Visit 5		Visit 6	
Stat		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Body Temperature (Celcius)	n	4	1	2	0	4	NA	4	1	4	0
	Mean (sd)	36.55 (0.26)	37 (NA)	36.1 (0.28)	NaN (NA)	36.3 (0.47)	NA	36.35 (0.76)	36.5 (NA)	36.25 (0.41)	NaN (NA)
	Median	36.6	37	36.1	NA	36.35	NA	36.25	36.5	36.2	NA
	IQR	(36.35, 36.75)	(37, 37)	(35.9, 36.3)	(NA, NA)	(35.95, 36.65)	NA	(35.75, 36.95)	(36.5, 36.5)	(35.9, 36.6)	(NA, NA)
	Range	(36.2, 36.8)	(37, 37)	(35.9, 36.3)	(Inf, -Inf)	(35.7, 36.8)	NA	(35.6, 37.3)	(36.5, 36.5)	(35.9, 36.7)	(Inf, -Inf)
Diastolic Blood Pressure (mmHg)	n	4	1	2	0	4	NA	4	1	4	0
	Mean (sd)	70.75 (10.87)	79 (NA)	73 (15.56)	NaN (NA)	77.25 (11.27)	NA	72.5 (11.73)	85 (NA)	72.75 (12.28)	NaN (NA)
	Median	67.5	79	73	NA	77.5	NA	71.5	85	71	NA
	IQR	(63, 78.5)	(79, 79)	(62, 84)	(NA, NA)	(67.5, 87)	NA	(62.5, 82.5)	(85, 85)	(62.5, 83)	(NA, NA)
	Range	(62, 86)	(79, 79)	(62, 84)	(Inf, -Inf)	(67, 87)	NA	(62, 85)	(85, 85)	(62, 87)	(Inf, -Inf)
Heart Rate (beats per minute)	n	4	1	2	0	4	NA	4	1	4	0
	Mean (sd)	86.5 (2.38)	87 (NA)	79.5 (6.36)	NaN (NA)	78.5 (11.03)	NA	75.5 (5.51)	101 (NA)	70.25 (8.54)	NaN (NA)
	Median	86.5	87	79.5	NA	73.5	NA	75	101	66.5	NA
	IQR	(84.5, 88.5)	(87, 87)	(75, 84)	(NA, NA)	(72.5, 84.5)	NA	(71, 80)	(101, 101)	(65.5, 75)	(NA, NA)
	Range	(84, 89)	(87, 87)	(75, 84)	(Inf, -Inf)	(72, 95)	NA	(70, 82)	(101, 101)	(65, 83)	(Inf, -Inf)
Respiratory Rate (breaths per minute)	n	4	0	2	0	4	NA	4	1	4	0
	Mean (sd)	16.5 (1.73)	NaN (NA)	16 (1.41)	NaN (NA)	17 (0.82)	NA	17.75 (0.5)	14 (NA)	14.5 (2.89)	NaN (NA)
	Median	16	NA	16	NA	17	NA	18	14	14.5	NA
	IQR	(15.5, 17.5)	(NA, NA)	(15, 17)	(NA, NA)	(16.5, 17.5)	NA	(17.5, 18)	(14, 14)	(12, 17)	(NA, NA)
	Range	(15, 19)	(Inf, -Inf)	(15, 17)	(Inf, -Inf)	(16, 18)	NA	(17, 18)	(14, 14)	(12, 17)	(Inf, -Inf)
Systolic Blood Pressure (mmHg)	n	4	1	2	0	4	NA	4	1	4	0
	Mean (sd)	109.25 (11.62)	125 (NA)	112 (21.21)	NaN (NA)	115.5 (16.94)	NA	112.5 (10.85)	135 (NA)	115 (11.8)	NaN (NA)
	Median	106	125	112	NA	116.5	NA	108.5	135	113.5	NA
	IQR	(100.5, 118)	(125, 125)	(97, 127)	(NA, NA)	(101, 130)	NA	(105, 120)	(135, 135)	(105, 125)	(NA, NA)
	Range	(100, 125)	(125, 125)	(97, 127)	(Inf, -Inf)	(98, 131)	NA	(105, 128)	(135, 135)	(105, 128)	(Inf, -Inf)
Weight (kg)	n	0	0	0	0	0	NA	0	0	0	0
	Mean (sd)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NA	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)
	Median	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	IQR	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	NA	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
	Range	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	NA	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)

Table 11. Summary of vital sign results, visits 7-10

		Visit 7		Visit 8		Visit 9		Visit 10	
Stat		GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)	GSK1070806 (N=4)	Placebo (N=1)
Body Temperature (Celcius)	n	4	1	4	1	2	1	1	1
	Mean (sd)	36.27 (0.32)	37.3 (NA)	36.2 (0.42)	36.4 (NA)	36.4 (0.57)	37.4 (NA)	36.4 (NA)	36.8 (NA)
	Median	36.25	37.3	36.15	36.4	36.4	37.4	36.4	36.8
	IQR	(36, 36.55)	(37.3, 37.3)	(35.85, 36.55)	(36.4, 36.4)	(36, 36.8)	(37.4, 37.4)	(36.4, 36.4)	(36.8, 36.8)
	Range	(36, 36.6)	(37.3, 37.3)	(35.8, 36.7)	(36.4, 36.4)	(36, 36.8)	(37.4, 37.4)	(36.4, 36.4)	(36.8, 36.8)
Diastolic Blood Pressure (mmHg)	n	4	1	4	1	2	1	1	1
	Mean (sd)	71.25 (14.61)	88 (NA)	74.5 (10.21)	78 (NA)	84 (4.24)	77 (NA)	79 (NA)	79 (NA)
	Median	70.5	88	74.5	78	84	77	79	79
	IQR	(60, 82.5)	(88, 88)	(68, 81)	(78, 78)	(81, 87)	(77, 77)	(79, 79)	(79, 79)
	Range	(55, 89)	(88, 88)	(62, 87)	(78, 78)	(81, 87)	(77, 77)	(79, 79)	(79, 79)
Heart Rate (beats per minute)	n	4	1	4	1	2	1	1	1
	Mean (sd)	76.75 (9.03)	89 (NA)	81 (6.68)	78 (NA)	83.5 (2.12)	97 (NA)	77 (NA)	102 (NA)
	Median	78	89	80	78	83.5	97	77	102
	IQR	(70, 83.5)	(89, 89)	(75.5, 86.5)	(78, 78)	(82, 85)	(97, 97)	(77, 77)	(102, 102)
	Range	(65, 86)	(89, 89)	(75, 89)	(78, 78)	(82, 85)	(97, 97)	(77, 77)	(102, 102)
Respiratory Rate (breaths per minute)	n	4	1	4	1	2	1	1	1
	Mean (sd)	16.75 (2.22)	17 (NA)	15.25 (2.22)	16 (NA)	15 (1.41)	17 (NA)	18 (NA)	19 (NA)
	Median	16	17	16	16	15	17	18	19
	IQR	(15.5, 18)	(17, 17)	(14, 16.5)	(16, 16)	(14, 16)	(17, 17)	(18, 18)	(19, 19)
	Range	(15, 20)	(17, 17)	(12, 17)	(16, 16)	(14, 16)	(17, 17)	(18, 18)	(19, 19)
Systolic Blood Pressure (mmHg)	n	4	1	4	1	2	1	1	1
	Mean (sd)	107.5 (14.06)	127 (NA)	115.25 (12.04)	108 (NA)	124.5 (2.12)	125 (NA)	123 (NA)	121 (NA)
	Median	107.5	127	113.5	108	124.5	125	123	121
	IQR	(96, 119)	(127, 127)	(105.5, 125)	(108, 108)	(123, 126)	(125, 125)	(123, 123)	(121, 121)
	Range	(92, 123)	(127, 127)	(104, 130)	(108, 108)	(123, 126)	(125, 125)	(123, 123)	(121, 121)
Weight (kg)	n	0	0	4	1	0	0	0	0
	Mean (sd)	NaN (NA)	NaN (NA)	59.15 (16.91)	74.9 (NA)	NaN (NA)	NaN (NA)	NaN (NA)	NaN (NA)
	Median	NA	NA	53.25	74.9	NA	NA	NA	NA
	IQR	(NA, NA)	(NA, NA)	(49.35, 68.95)	(74.9, 74.9)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
	Range	(Inf, -Inf)	(Inf, -Inf)	(46.1, 84)	(74.9, 74.9)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)	(Inf, -Inf)

f) Frequency, type and severity of infections

Table 12: Summary of Infections reported during the trial

Treatment	Category	Toxicity	Grade	Time to onset (months)	Ongoing	Length of Infection (days)	Causality	Pre-Existing	SAE	Liver Toxicity
GSK1070806	Infections and infestations	Other, specify: shivers	1	3.71	No	1	Unrelated	No	No	No
GSK1070806	Infections and infestations	Other, specify: Athletes foot - left	1	1.52	No	9	Unrelated	No	No	No

Key Secondary outcome measure

CDAI score over time

Table 13: Summary of CDAI score over time, by visit and treatment allocation

Visit	Daily Abdominal Pain	GSK1070806 (N=4)	Placebo (N=1)
Visit 1	n	4	1
	Mean (sd)	120.5 (18.86)	200 (NA)
	Median	117	200
	IQR	(109.5, 128)	(200, 200)
	Range	(102, 146)	(200, 200)
Visit 2	n	4	1
	Mean (sd)	114.75 (34.33)	200 (NA)
	Median	120.5	200
	IQR	(104, 131.25)	(200, 200)
	Range	(68, 150)	(200, 200)
Visit 3	n	4	1
	Mean (sd)	108 (22.85)	245 (NA)
	Median	117.5	245
	IQR	(105.5, 120)	(245, 245)
	Range	(74, 123)	(245, 245)
Visit 4	n	4	1
	Mean (sd)	97.5 (32.13)	211 (NA)
	Median	101.5	211
	IQR	(82.25, 116.75)	(211, 211)
	Range	(56, 131)	(211, 211)
Visit 5	n	4	1
	Mean (sd)	102.75 (16.88)	275 (NA)
	Median	109.5	275
	IQR	(99, 113.25)	(275, 275)
	Range	(78, 114)	(275, 275)
Visit 6	n	4	1
	Mean (sd)	93.75 (17.82)	
	Median	96.5	
	IQR	(86.5, 103.75)	
	Range	(70, 112)	
Visit 7	n	4	1
	Mean (sd)	89.5 (26.08)	28 (NA)
	Median	96	28
	IQR	(80.75, 104.75)	(28, 28)
	Range	(53, 113)	(28, 28)
Visit 8	n	4	1
	Mean (sd)	98 (40.91)	74 (NA)
	Median	89.5	74
	IQR	(74, 113.5)	(74, 74)
	Range	(59, 154)	(74, 74)
Visit 9	n	2	1
	Mean (sd)	94 (14.14)	59 (NA)
	Median	94	59
	IQR	(89, 99)	(59, 59)
	Range	(84, 104)	(59, 59)
Visit 10	n	1	1
	Mean (sd)	70 (NA)	80 (NA)
	Median	70	80
	IQR	(70, 70)	(80, 80)
	Range	(70, 70)	(80, 80)

Adverse Events

Table 14. Number of patients affected by adverse events according to CTCAE toxicity and grade, by treatment

Category	Toxicity	GK1070805 (N=4)				Placebo (N=1)		
		Grade 1	Grade 2	Grade 3	Grade Not Known	Grade 1	Grade 2	Grade 3
Blood and lymphatic system disorders	Other, specify: Abnormal albumin	1	0	0	0	0	0	0
	Other, specify: Abnormal blood cells dist width	1	0	0	0	0	0	0
	Other, specify: Abnormal lymphocytes	1	0	0	0	0	0	0
	Other, specify: Abnormal mean cell volume	1	0	0	0	0	0	0
	Other, specify: Abnormal total protein	1	0	0	0	0	0	0
	Other, specify: Abnormal urea, low	1	0	0	0	0	0	0
	Other, specify: Decreased albumin	1	0	0	0	0	0	0
	Other, specify: Decreased aptt	1	0	0	0	0	0	0
	Other, specify: Decreased calcium baseline	1	0	0	0	0	0	0
	Other, specify: Decreased mean cell hb	1	0	0	0	0	0	0
	Other, specify: Decreased mean cell volumne	1	0	0	0	0	0	0
	Other, specify: Decreased ptp	1	0	0	0	0	0	0
	Other, specify: Decreased urea	1	0	0	0	0	0	0
	Other, specify: Drop in haematocrit	1	0	0	0	0	0	0
	Other, specify: Drop in hb	1	0	0	0	0	0	0
	Other, specify: Elevated crp	1	1	0	0	0	0	0
	Other, specify: lcreased rbc distance width	1	0	0	0	0	0	0
	Other, specify: Increase in basophils	1	0	0	0	0	0	0
	Other, specify: Increase in eosinophils	1	0	0	0	0	0	0
	Other, specify: Increase in platelet dist width	1	0	0	0	0	0	0
	Other, specify: Increased rbc dist width baseline	0	0	0	1	0	0	0
	Other, specify: Increased cholesterol	1	0	0	0	0	0	0
	Other, specify: Increased platelets	1	0	0	0	0	0	0
	Other, specify: Increased rbc dist width	1	0	0	0	0	0	0
	Other, specify: Low albumin	2	0	0	0	0	0	0
	Other, specify: Low basophils	1	0	0	0	0	0	0
	Other, specify: Low calcium	2	0	0	0	0	0	0
	Other, specify: Low creatinine kinase	1	0	0	0	0	0	0
	Other, specify: Low haematocrit	1	0	0	0	0	0	0

Category	Toxicity	GK1070805 (N=4)				Placebo (N=1)		
		Grade 1	Grade 2	Grade 3	Grade Not Known	Grade 1	Grade 2	Grade 3
	Other, specify: Low hb	1	0	0	0	0	0	0
	Other, specify: Low mean cell hb	1	0	0	0	0	0	0
	Other, specify: Low mean cell hb conc	1	0	0	0	0	0	0
	Other, specify: Low neutrophil count	1	0	0	0	0	0	0
	Other, specify: Low red cell count	1	0	0	0	0	0	0
	Other, specify: Low serum folate	1	0	0	0	0	0	0
	Other, specify: Low total protein	1	0	0	0	0	0	0
	Other, specify: Low urea	1	0	0	0	0	0	0
	Other, specify: Low vitamin d	0	1	0	0	0	0	0
	Other, specify: Low wbc	1	0	0	0	0	0	0
	Other, specify: Mean cell hb conc	1	0	0	0	0	0	0
	Other, specify: Moderately elevated crp	0	1	0	0	0	0	0
	Other, specify: Raised alphafetoprotein	0	1	0	0	0	0	0
	Other, specify: Raised ast	1	0	0	0	0	0	0
	Other, specify: Raised esr	1	0	0	0	0	0	0
	Other, specify: Raised rbc	1	0	0	0	0	0	0
	Other, specify: Raised total protein	1	0	0	0	0	0	0
Cardiac disorders	Other, specify: Sinus arrhythmia	0	0	0	0	1	0	0
	Other, specify: Sinus rhythm with short pr interval	1	0	0	0	0	0	0
Eye disorders	Conjunctivitis	1	0	0	0	0	0	0
	Other, specify: Cysts on lower left eye lid	0	1	0	0	0	0	0
Gastrointestinal disorders	Abdominal pain	1	1	0	0	0	0	1
	Diarrhea	1	0	0	0	0	0	0
	Dyspepsia	1	0	0	0	0	0	0
	Nausea	1	0	1	0	1	0	0
	Other, specify: Abdominal lump	1	0	0	0	0	0	0
	Other, specify: Elevated faecal calprotectin	1	0	0	0	0	0	0
	Other, specify: Increased faecal calprotectin	0	1	0	0	0	0	0
	Other, specify: Moderately raised faecal calprotectin	0	1	0	0	0	0	0
	Other, specify: Mouth ulcer, left side tongue	1	0	0	0	0	0	0
	Other, specify: Raised faecal calprotectin	1	0	0	0	0	0	0
	Other, specify: Raised faecal calprotectin	1	0	0	0	0	0	0
	Other, specify: Raised faecal calprotectin	1	0	0	0	0	0	0

Category	Toxicity	GK1070805 (N=4)				Placebo (N=1)		
		Grade 1	Grade 2	Grade 3	Grade Not Known	Grade 1	Grade 2	Grade 3
	Other, specify: Sore throat	1	0	0	0	0	0	0
	Other, specify: Very high faecal calprotectin	0	0	1	0	0	0	0
	Vomiting	0	0	0	0	1	0	0
General disorders and administration site conditions	Fatigue	0	0	1	0	0	0	0
	Fever	1	0	0	0	0	0	0
	Other, specify: Blackout	1	0	0	0	0	0	0
	Other, specify: Headache	1	0	0	0	0	0	0
	Other, specify: Tiredness	1	0	0	0	0	0	0
Infections and infestations	Other, specify: Athletes foot - left	1	0	0	0	0	0	0
	Other, specify: Shivers	1	0	0	0	0	0	0
Investigations	Aspartate aminotransferase increased	1	0	0	0	0	0	0
	Other, specify: C reactive protein (crp) increased	1	0	0	0	0	0	0
	Other, specify: Faecal calprotectin increased	1	0	0	0	0	0	0
	Other, specify: Haematocrit decreased	1	0	0	0	0	0	0
	Other, specify: Haemoglobin decreased	1	0	0	0	0	0	0
	Other, specify: Immunoglobulin igm decreased	1	0	0	0	0	0	0
	Other, specify: Red cell count decreased	1	0	0	0	0	0	0
	Other, specify: Reduced albumin	1	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	Other, specify: ? Viral aches and pains in thighs and to ps of arms – intermittent	1	0	0	0	0	0	0
	Other, specify: Aches in thighs	0	1	0	0	0	0	0
	Other, specify: Joint pain- intermittent	1	0	0	0	0	0	0
	Other, specify: Joint pains	0	0	1	0	0	0	0
	Other, specify: Upper arms aches	0	1	0	0	0	0	0
Nervous system disorders	Lethargy	1	0	0	0	0	0	0
	Other, specify: All over body tingling sensation	0	1	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	Cough	1	0	0	0	0	0	0
	Other, specify: Cold, felt feverish, sore throat and running nose	0	1	0	0	0	0	0
	Other, specify: Runny nose	1	0	0	0	0	0	0
	Other, specify: Viral upper respiratory tract infection	1	0	0	0	0	0	0
Skin and subcutaneous	Other, specify: Bruising at cannula site right wrist	0	1	0	0	0	0	0

Category	Toxicity	GK1070805 (N=4)				Placebo (N=1)		
		Grade 1	Grade 2	Grade 3	Grade Not Known	Grade 1	Grade 2	Grade 3
tissue disorders	Other, specify: Bruising, left wrist , cannula site	0	1	0	0	0	0	0
	Other, specify: Sensitive skin	1	0	0	0	0	0	0
	Other, specify: Two small scabs on lower abdo, below belly button, caused by using radox bath cream	0	0	0	0	1	0	0

Table 15: Line listing of Serious Adverse Events reporting during the trial

Time to onset (from randomisation)	SAE Reason	Trt	Description	Category	Toxicity	Grade	Other Events	Relatedness	SAE Cat	Outcome	SAE Duration	Event Details	Relevant Medical History
16 Days	Hospitalisation;	Placebo	lower right quadrant pain	Gastrointestinal disorders	Abdominal pain	2		Unrelated	Unrelated SAE	Resolved - no sequelae	1 Day	Right sided abdominal pain, pain for 4 days, bowels opened whenever she eats No blood or nausea. On examination, very tender right iliac fossa with guarding. Chest clear. ECG showed new arrhythmia - admitted for investigations to rule out collections.	Vitamin B12 deficiency, anaemia, migraine, other chronic pulmonary disease, CD of large intestine, dermatitis and eczema.
19 Days	Hospitalisation;	GSK1070 806		Gastrointestinal disorders	Abdominal pain	1	Nausea (Gastrointestinal disorders, Grade 1)	Unlikely to be related	Unrelated SAE	Resolved - no sequelae	1 Day	Upper abdominal pain with nausea for a duration of 10 days (start date 16-Oct-2019). Attended the clinical research facility on 29-Oct- 2019 for visit 5. Following this, sent to clinical decision unit for CT scan.	Crohn's Disease. On clinical trial involving one dose of medication given on 14-oct-2019.