Clinical trial results:
A Single Blind (Sponsor-unblinded), Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of GSK1070806 in the Treatment of Obese Subjects with T2DM.

Summary

EudraCT number	2012-000126-22
Trial protocol	GB ES
Global end of trial date	03 January 2014

Results information

Result version number	v1 (current)
This version publication date	08 March 2016
First version publication date	24 May 2015

Trial information

Trial identification

Sponsor protocol code	A18116378

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, +1 8664357343,
Scientific contact	GSK Response Center, GlaxoSmithKline, +1 8664357343,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 September 2013
Global end of trial reached?	Yes
Global end of trial date	03 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of two repeat intravenous dose administrations of GSK1070806 in subjects with T2DM.

Protection of trial subjects:

The study design allowed for a long observational period following the first dose to monitor any adverse events (AEs) prior to administration of a second dose. Based on the half-life of the molecule, significant accumulation of drug following the administration of a second dose was not expected. The study had a long follow-up (out to Day 210) to monitor for the appearance of treatment-related AEs.

All participants were rigorously screened by clinical examination for ongoing or potentially emergent infections by a physician at the screening visit, prior to dosing, and during the course of the study. Viral screening methods were employed at screening. Participants who tested positive for any of the following were excluded from the study: Hepatitis B, Hepatitis C, human immunodeficiency virus (HIV).

Participants with current evidence of acute or ongoing infection and a history of repeated, chronic, or opportunistic infections (viral, bacterial, or fungal) were excluded. Where possible, inactivated flu vaccine was administered at screening prior to starting treatment with study medication and in accordance with local practices.

Given the hypothetical role of IL-18 in the potentiation of immune surveillance of nascent tumours, participants with a history of malignancy were excluded from the study.

Eligible women of childbearing potential were allowed to participate in the trial at study sites where regulation allows for their inclusion. They were requied to use contraception for approximately 30 weeks after the first dose or up to Study Day 210.

Participants were advised to refrain from travelling to countries where there is a high incidence of infectious diseases until the study follow-up visit on Day 210. By Day 210, the effects on IFNinhibition in the obese population was predicted to be minimal; therefore, little or no impact on the participants' immunity to infection would be anticipated after this time period.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 August 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	29
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study consisted of screening and a 4-week treatment period (sponsor-unblinded, placebo-controlled). Obese participants with Type 2 Diabetes Mellitus who remained on their current diet and dose of metformin were enrolled.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo via intravenous (IV) infusion on the Day 1 and Day 29 study visits.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dosing on Days 1 and 29, by 60 minute infusion. Volume matched to active treatment.

Arm title	GSK1070806 0.25 mg/kg

Arm description:

Participants received GSK1070806 0.25 milligrams per kilogram (mg/kg) via IV infusion on the Day 1 and Day 29 study visits.

Arm type	Experimental
Investigational medicinal product name	GSK1070806
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dosing on Days 1 and 29, at 0.25 mg/kg, by 60 minute infusion

Arm title	GSK1070806 5 mg/kg

Arm description:

Participants received GSK1070806 5 mg/kg via IV infusion on the Day 1 and Day 29 study visits.

Arm type	Experimental
Investigational medicinal product name	GSK1070806
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Dosing on Days 1 and 29, at 5 mg/kg, by 60 minute infusion

Number of subjects in period 1	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg
Started	12	13	12
Completed	12	13	12

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo via intravenous (IV) infusion on the Day 1 and Day 29 study visits.	
Reporting group title	GSK1070806 0.25 mg/kg
Reporting group description:	
Participants received GSK1070806 0.25 milligrams per kilogram (mg/kg) via IV infusion on the Day 1 and Day 29 study visits.	
Reporting group title	GSK1070806 5 mg/kg
Reporting group description:	
Participants received GSK1070806 5 mg/kg via IV infusion on the Day 1 and Day 29 study visits.	

Reporting group values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg
Number of subjects	12	13	12
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	55.1	58	58.7
standard deviation	± 9.61	± 9.57	± 7.97
Gender categorical Units: Subjects			
Female	2	4	3
Male	10	9	9
Race, customized Units: Subjects			
White	12	13	12

Reporting group values	Total		
Number of subjects	37		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		

Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	9		
Male	28		
Race, customized			
Units: Subjects			
White	37		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo via intravenous (IV) infusion on the Day 1 and Day 29 study visits.	
Reporting group title	GSK1070806 0.25 mg/kg
Reporting group description:	
Participants received GSK1070806 0.25 milligrams per kilogram (mg/kg) via IV infusion on the Day 1 and Day 29 study visits.	
Reporting group title	GSK1070806 5 mg/kg
Reporting group description:	
Participants received GSK1070806 5 mg/kg via IV infusion on the Day 1 and Day 29 study visits.	

Primary: Change from Baseline in fasting plasma glucose (FPG) level on Days 29, 57, and 85

End point title	Change from Baseline in fasting plasma glucose (FPG) level on Days 29, 57, and 85
End point description:	
The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. Change from Baseline in FPG was compared between treatment groups using repeated measures analysis with fixed effects for Baseline, visit, and Baseline by visit. The Baseline FPG value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. If pre-dose FPG values (labortory data) were missing, then values were imputed using pre-mixed meal test (MMT) glucose values (biomarker data).	
End point type	Primary
End point timeframe:	
Baseline; Days 29, 57, and 85	

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[1]	13[2]	12[3]	
Units: Millimoles per liter (mmol/L)				
least squares mean (standard error)				
Day 29	-0.047 (± 0.3851)	-0.471 (± 0.3689)	-0.05 (± 0.3799)	
Day 57	-0.755 (± 0.4645)	-0.409 (± 0.4454)	-1.133 (± 0.4603)	
Day 85	-0.555 (± 0.584)	-0.024 (± 0.5604)	-0.591 (± 0.5806)	

Notes:

[1] - All Subject Population: all participants who received study drug

[2] - All Subject Population: all participants who received study drug

[3] - All Subject Population: all participants who received study drug

Statistical analyses

Statistical analysis title	Day 29; Placebo:GSK1070806 0.25 mg/kg
Comparison groups	Placebo v GSK1070806 0.25 mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4376
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.424
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.519
upper limit	0.672

Statistical analysis title	Day 57; Placebo:GSK1070806 0.25 mg/kg
Comparison groups	Placebo v GSK1070806 0.25 mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5973
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.346
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.975
upper limit	1.667

Statistical analysis title	Day 85; Placebo:GSK1070806 0.25 mg/kg
Comparison groups	Placebo v GSK1070806 0.25 mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5186
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.531
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.125
upper limit	2.186

Statistical analysis title	Day 29; Placebo:GSK1070806 5 mg/kg
Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.996
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.003
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.103
upper limit	1.097

Statistical analysis title	Day 57; Placebo:GSK1070806 5 mg/kg
Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5677
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.378
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.711
upper limit	0.956

Statistical analysis title	Day 85; Placebo:GSK1070806 5 mg/kg
Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9653
Method	Mixed Model Repeated Measures Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.036

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.713
upper limit	1.641

Primary: Change from Baseline in weighted mean glucose area under the concentration-time curve from time zero (pre-dose) to 4 hours (AUC[0 4hrs]) post-Mixed Meal Test (MMT) on Days 29, 57, and 85

End point title	Change from Baseline in weighted mean glucose area under the concentration-time curve from time zero (pre-dose) to 4 hours (AUC[0 4hrs]) post-Mixed Meal Test (MMT) on Days 29, 57, and 85

End point description:

The weighted mean parameters were derived by calculating the area under the curve (AUC, which reflects the actual body exposure to drug after administration of a dose of the drug) using the trapezoidal rule, and then dividing by the actual relevant time interval (i.e., actual time point [hrs] of the first non-missing observation [in planned time tf=0 hour] minus the actual time point [hrs] of the last non-missing observation [e.g., in planned time for glucose, tl=240 minutes]). Change from Baseline in weighted mean AUC(0-4hrs) post-MMT profiles for glucose was compared between treatment groups using repeated measures analysis with fixed effects for Baseline, visit, and Baseline by visit. The Baseline weighted mean glucose value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. If pre-MMT glucose values (biomarker data) were missing, then values were imputed using pre-dose FPG values (laboratory data).

End point type	Primary

End point timeframe:

Baseline; Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[4]	13[5]	12[6]	
Units: mmol/L				
least squares mean (standard error)				
Day 29	0.09 (± 0.42)	-0.43 (± 0.407)	-0.43 (± 0.407)	
Day 57	-0.47 (± 0.518)	-0.43 (± 0.5)	-1.28 (± 0.508)	
Day 85	-0.48 (± 0.588)	-0.3 (± 0.567)	-0.76 (± 0.579)	

Notes:

[4] - All Subject Population

[5] - All Subject Population

[6] - All Subject Population

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Day 29

Comparison groups	Placebo v GSK1070806 0.25 mg/kg

Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.75
upper limit	0.71

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Day 57	
Comparison groups	Placebo v GSK1070806 0.25 mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.46
upper limit	1.53

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Day 85	
Comparison groups	Placebo v GSK1070806 0.25 mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.87

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Day 29	

Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	0.67

Statistical analysis title	Statistical analysis 5
Statistical analysis description: Day 57	
Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.28
upper limit	0.66

Statistical analysis title	Statistical analysis 6
Statistical analysis description: Day 85	
Comparison groups	Placebo v GSK1070806 5 mg/kg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.95
upper limit	1.39

Secondary: Number of participants with any adverse event (AE) and any serious adverse event (SAE)

End point title	Number of participants with any adverse event (AE) and any serious adverse event (SAE)

End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death; was life threatening; required hospitalization or prolongation of existing hospitalization; resulted in disability/incapacity; was a congenital anomaly/birth defect.

End point type	Secondary

End point timeframe:

From Baseline until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[7]	13[8]	12[9]	
Units: Participants				
number (not applicable)				
Any AE	11	12	11	
Any SAE	1	0	1	

Notes:

[7] - All Subject Population (ASP)

[8] - All Subject Population (ASP)

[9] - All Subject Population (ASP)

Statistical analyses

No statistical analyses for this end point

Secondary: Albumin and total protein values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Albumin and total protein values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Albumin and total protein values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[10]	13[11]	12[12]	
Units: Grams per liter (G/L)				
arithmetic mean (standard deviation)				
Albumin, Screening, n=12, 13, 12	47.1 (± 4.62)	45.9 (± 3.33)	45.4 (± 2.64)	

Albumin, Day 1: pre-dose, n=12, 12, 12	44.7 (± 3.42)	43.3 (± 3.14)	45 (± 2.59)	
Albumin, Day 1: 4 hr, n=11, 12, 11	42 (± 4.98)	42.5 (± 3.68)	42.4 (± 2.25)	
Albumin, Day 4, n=11, 12, 11	46.8 (± 3.31)	44.9 (± 2.06)	45.6 (± 2.87)	
Albumin, Day 9, n=12, 13, 12	46.4 (± 3.53)	45.2 (± 2.13)	44.8 (± 3.17)	
Albumin, Day 14, n=12, 13, 12	47.1 (± 4.29)	44.7 (± 2.78)	44.8 (± 2.69)	
Albumin, Day 21, n=12, 13, 12	45.9 (± 4.19)	44.6 (± 2.57)	45.3 (± 2.93)	
Albumin, Day 29: pre-dose, n=11, 13, 12	44.6 (± 4.25)	44 (± 4.22)	44.9 (± 2.97)	
Albumin, Day 29: 4 hr, n=12, 10, 11	42.5 (± 3.18)	42.3 (± 5.6)	42.2 (± 2.86)	
Albumin, Day 32: n=11, 13, 12	46.5 (± 2.91)	45.5 (± 2.85)	45.3 (± 2.86)	
Albumin, Day 42: n=12, 13, 12	46.7 (± 2.81)	44.8 (± 2.42)	46 (± 2.63)	
Albumin, Day 57: n=12, 13, 12	45.7 (± 2.53)	44.2 (± 3.89)	45.7 (± 2.19)	
Albumin, Day 85: n=11, 12, 12	45.4 (± 3.29)	45.8 (± 3.01)	45.3 (± 2.56)	
Albumin, Day 120: n=11, 13, 12	46 (± 2.9)	44.5 (± 2.96)	45 (± 3.3)	
Albumin, Day 165: n=12, 12, 12	45.5 (± 3.06)	44.8 (± 2.49)	44.1 (± 3.5)	
Albumin, follow-up: n=12, 12, 12	45.6 (± 3.4)	44.1 (± 3.12)	44.3 (± 1.86)	
Total protein, Screening: n=12, 13, 12	73.3 (± 4.79)	72.3 (± 4.4)	72.1 (± 4.96)	
Total protein, Day 1: pre-dose, n=12, 12, 12	69.8 (± 4.3)	69.4 (± 5.04)	70.6 (± 3.99)	
Total protein, Day 1: 4 hr, n=11, 12, 11	66.3 (± 7.77)	67.8 (± 3.79)	67.5 (± 3.56)	
Total protein, Day 4: n=11, 13, 11	73.5 (± 4.82)	70.2 (± 2.48)	71.2 (± 4.9)	
Total protein, Day 9: n=12, 13, 12	72.7 (± 4.5)	70.3 (± 2.9)	71.7 (± 5.14)	
Total protein, Day 14: n=12, 13, 12	73.6 (± 4.85)	70.2 (± 3.35)	71.7 (± 5.79)	
Total protein, Day 21: n=12, 13, 12	71.7 (± 4.03)	70.2 (± 3.06)	71.3 (± 4.52)	
Total protein, Day 29: pre-dose, n=11, 13, 12	70 (± 6.87)	68.5 (± 5.98)	70.3 (± 5)	
Total protein, Day 29: 4 hr, n=12, 10, 11	67.1 (± 5.68)	67.3 (± 6)	65.9 (± 4.93)	
Total protein, Day 32: n=11, 13, 12	72.4 (± 3.64)	71.5 (± 2.44)	71.3 (± 3.82)	
Total protein, Day 42: n=12, 13, 12	72.8 (± 4.15)	70.2 (± 2.45)	70.9 (± 4.38)	
Total protein, Day 57: n=12, 13, 12	72 (± 2.73)	68.5 (± 5.58)	71.1 (± 4.25)	
Total protein, Day 85: n=11, 12, 12	72.1 (± 2.91)	71.3 (± 5.3)	70.3 (± 4.96)	
Total protein, Day 120: n=11, 13, 12	73.3 (± 4.47)	70.2 (± 3.21)	71 (± 5.44)	
Total protein, Day 165: n=12, 12, 12	72.3 (± 2.96)	70.8 (± 3.36)	70.5 (± 5.14)	
Total protein, follow-up: n=12, 11, 12	73.2 (± 4.11)	69.9 (± 3.59)	70.8 (± 3.67)	

Notes:

[10] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[11] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[12] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: ALP, ALT, AST, and GGT values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (FU)

End point title	ALP, ALT, AST, and GGT values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (FU)

End point description:

Alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma glutamyl transferase (GGT) values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[13]	13[14]	12[15]	
Units: International Units per liter (IU/L)				
arithmetic mean (standard deviation)				
ALP, Screening, n=12, 13, 12	78.5 (± 23.65)	66.8 (± 13.39)	76.6 (± 25.72)	
ALP, Day 1: pre-dose, n= 12, 12, 12	74.5 (± 22.15)	63.7 (± 17.03)	69.9 (± 20.08)	
ALP, Day 1: 4 hr, n=11, 12, 11	71.4 (± 22.01)	62.9 (± 12.67)	68.5 (± 23.11)	
ALP, Day 4, n=11, 13, 11	83.4 (± 27.58)	64.2 (± 14.29)	73.6 (± 21.64)	
ALP, Day 9, n=12, 13, 12	79.6 (± 25.45)	66.2 (± 14.28)	70.2 (± 18.5)	
ALP, Day 14, n=12, 13, 12	79.3 (± 23.26)	62.1 (± 14.74)	71.9 (± 19.72)	
ALP, Day 21, n=12, 13, 12	77.1 (± 22.92)	63.7 (± 12.4)	74.9 (± 23.38)	
ALP, Day 29: pre-dose, n=11, 13, 12	74 (± 25.25)	63.5 (± 16.61)	74.3 (± 24.73)	
ALP, Day 29: 4 hr, n=12, 10, 11	72.8 (± 20.77)	57.1 (± 12.93)	71.7 (± 25.78)	
ALP, Day 32, n=11, 13, 12	83.4 (± 24.43)	64.2 (± 12.84)	75.5 (± 26.22)	
ALP, Day 42, n=12, 13, 12	80.4 (± 22.91)	61.3 (± 12.05)	71.7 (± 23)	
ALP, Day 57, n=12, 13, 12	78.1 (± 23.54)	59.8 (± 12.07)	70 (± 17.66)	
ALP, Day 85, n=11,12, 12	79.8 (± 20.85)	66.7 (± 12.46)	69.7 (± 19.12)	
ALP, Day 120, n=11, 13, 12	75 (± 21.67)	65.8 (± 13.86)	72.8 (± 20.97)	
ALP, Day 165, n=12, 12, 12	79.5 (± 23.73)	62.1 (± 13.12)	69.7 (± 20.22)	
ALP, follow-up, n=12, 12, 12	81.8 (± 22.68)	64.3 (± 16.74)	74.1 (± 18.88)	
ALT, Screening, n=12, 13, 12	34.3 (± 21.24)	27.9 (± 20.73)	28.4 (± 13.14)	
ALT, Day 1: pre-dose, n=12, 12, 12	30.7 (± 19.78)	26.3 (± 13.14)	26.2 (± 12.68)	
ALT, Day 1: 4 hr, n=11, 12, 11	29.4 (± 20.58)	28.6 (± 18.56)	26.5 (± 11.83)	
ALT, Day 4, n=11, 13, 11	32.2 (± 24.06)	29.6 (± 18.04)	27.4 (± 14.32)	
ALT, Day 9, n=12, 13, 12	31.8 (± 22.03)	26.3 (± 18.21)	25.7 (± 11.26)	
ALT, Day 14, n=12, 13, 12	30.3 (± 17.57)	25.5 (± 14.23)	29.9 (± 16.47)	
ALT, Day 21, n=12, 13, 12	29.3 (± 15.51)	25.7 (± 15.62)	31.3 (± 20.44)	
ALT, Day 29: pre-dose, n=11, 13, 12	26.7 (± 15.25)	25.4 (± 15.44)	28 (± 20.1)	
ALT, Day 29: 4 hr, n=12, 10, 11	25.8 (± 15)	24.5 (± 15.15)	26 (± 19.88)	
ALT, Day 32, n=11, 13, 12	29.2 (± 17.53)	26.2 (± 15.36)	27.7 (± 16.14)	
ALT, Day 42, n=12, 13, 12	26.3 (± 12.91)	25.2 (± 16.05)	21.6 (± 9.95)	
ALT, Day 57, n=12, 13, 12	27.8 (± 16.27)	27.1 (± 23.17)	24.1 (± 12.09)	
ALT, Day 85, n=11, 12, 12	23.6 (± 13.97)	28.3 (± 19.11)	22.3 (± 12.14)	
ALT, Day 120, n=11, 13, 12	28.3 (± 17.23)	27.2 (± 20)	24.1 (± 11.45)	
ALT, Day 165, n=12, 12, 12	25.8 (± 15.01)	28.3 (± 16.74)	29.8 (± 16.82)	
ALT, follow-up, n=12, 12, 12	28.8 (± 20.26)	27.7 (± 16.29)	26.2 (± 19.69)	
AST, Screening, n=12, 13, 12	28.3 (± 15.52)	23.1 (± 7.64)	30.3 (± 22.34)	
AST, Day 1: pre-dose, n=12, 12, 12	24.3 (± 11.24)	23.4 (± 6.57)	32.3 (± 22.5)	
AST, Day 1: 4 hr, n= 11, 12, 11	23.5 (± 12.19)	25.5 (± 11.71)	32.1 (± 20.6)	
AST, Day 4, n=11, 13, 11	26.9 (± 15.48)	28 (± 12.32)	29.3 (± 16.55)	
AST, Day 9, n=12, 13, 12	25.1 (± 11.58)	24.1 (± 11.15)	26.8 (± 12.74)	
AST, Day 14, n=12, 13, 12	23.8 (± 9.04)	23.4 (± 7.26)	31.3 (± 14.26)	
AST, Day 21, n=12, 13, 12	24 (± 8.34)	24.1 (± 11.51)	30.3 (± 15.99)	
AST, Day 29: pre-dose, n=11, 13, 12	23.9 (± 10.82)	24.5 (± 8.88)	26.8 (± 11.17)	

AST, Day 29: 4 hr, n=12, 10, 11	23.3 (± 10.69)	25.6 (± 10.89)	24.3 (± 12.55)	
AST, Day 32, n=11, 13, 12	25.6 (± 12.08)	26.5 (± 15.15)	26.1 (± 11.16)	
AST, Day 42, n=12, 13, 12	23.5 (± 8.57)	24.8 (± 11.04)	23.1 (± 7.22)	
AST, Day 57, n=12, 13, 12	23.5 (± 8.03)	27.2 (± 16.27)	26.4 (± 10.79)	
AST, Day 85, n=11, 12, 12	22 (± 7.04)	27.2 (± 12.3)	25.3 (± 9.39)	
AST, Day 120, n=11, 13, 12	24.7 (± 10.2)	27.8 (± 14.05)	25.5 (± 8.12)	
AST, Day 165, n=12, 12, 11	21.8 (± 7.31)	27.7 (± 16.04)	29.3 (± 15.43)	
AST, follow-up, n=12, 12, 12	23 (± 9.89)	30.2 (± 26.01)	30.6 (± 20.18)	
GGT, Screening, n=12, 13, 12	82.4 (± 91.07)	54.5 (± 44.72)	67.1 (± 78.69)	
GGT, Day 1: pre-dose, n=12, 12, 12	77.4 (± 93.11)	51.3 (± 49.89)	56.6 (± 63.91)	
GGT, Day 1: 4 hr, n=11, 12, 11	75.1 (± 92.04)	51.5 (± 40.97)	58.1 (± 64.05)	
GGT, Day 4, n=11, 13, 11	83.3 (± 114.1)	49.3 (± 39.21)	59.4 (± 59.95)	
GGT, Day 9, n=12, 13, 12	79.3 (± 98.99)	47.3 (± 37.47)	53.8 (± 54.12)	
GGT, Day 14, n=12, 13, 12	81.3 (± 104.94)	45.3 (± 34.15)	58.8 (± 70.41)	
GGT, Day 21, n=12, 13, 12	78.4 (± 102.85)	46.8 (± 34.7)	60.6 (± 76.89)	
GGT, Day 29: pre-dose, n=11, 13, 12	77.4 (± 86.33)	45.4 (± 34.77)	61.8 (± 78.46)	
GGT, Day 29: 4 hr, n=12, 10, 11	67.4 (± 79.37)	38.5 (± 30.31)	61.9 (± 86.34)	
GGT, Day 32, n=11, 13, 12	79.1 (± 87.28)	45.5 (± 33.09)	63.6 (± 80.35)	
GGT, Day 42, n=12, 13, 12	74.1 (± 87.81)	43.2 (± 30.1)	58.8 (± 69.92)	
GGT, Day 57, n=12, 13, 12	74.8 (± 84.94)	43 (± 30.35)	63.9 (± 87.39)	
GGT, Day 85, n=11, 12,12	76 (± 78.73)	50.7 (± 36.28)	54.8 (± 58.61)	
GGT, Day 120, n=11, 13, 12	76.5 (± 99.72)	51.8 (± 45.21)	55 (± 45.87)	
GGT, Day 165, n=12, 12, 12	68.1 (± 72.82)	54.2 (± 46.06)	54.3 (± 36.98)	
GGT, follow-up, n=12, 12, 12	81.5 (± 113.46)	52.4 (± 44.69)	51.5 (± 44.76)	

Notes:

[13] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[14] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[15] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Total bilirubin (TB), direct bilirubin (DB), uric acid, and creatinine values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Total bilirubin (TB), direct bilirubin (DB), uric acid, and creatinine values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

TB, DB, uric acid, and creatinine were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[16]	13[17]	12[18]	
Units: Micromoles per liter (µmol/L)				
arithmetic mean (standard deviation)				
TB, Screening, n=12, 13, 12	11.4 (± 5.18)	12.3 (± 9.45)	12.5 (± 4.91)	
TB, Day 1: pre-dose, n=12, 12, 12	10.6 (± 3.63)	12 (± 10.13)	10.6 (± 4.5)	
TB, Day 1: 4 hr, n= 11, 12, 11	10.4 (± 4.7)	12.8 (± 9.29)	11.5 (± 6.41)	
TB, Day 4, n=11, 13, 11	9.7 (± 3.41)	13.1 (± 8.87)	10.8 (± 4.94)	
TB, Day 9, n=12, 13, 12	11.1 (± 4.62)	11.6 (± 7.63)	11.4 (± 6.43)	
TB, Day 14, n=12, 13, 12	9.8 (± 3.89)	9.5 (± 4.98)	9.3 (± 3.42)	
TB, Day 21, n=12, 13, 12	10.6 (± 4.06)	11.2 (± 6.79)	9.1 (± 4.19)	
TB, Day 29: pre-dose, n=11, 13, 12	10.5 (± 4.74)	9.8 (± 6.92)	8 (± 3.72)	
TB, Day 29: 4 hr, n=12, 10, 11	9.3 (± 4.67)	11.2 (± 6.56)	9 (± 3.46)	
TB, Day 32, n=11, 13, 12	10.8 (± 4.62)	10.2 (± 5.51)	10.4 (± 3.96)	
TB, Day 42, n=12, 13, 12	9.4 (± 2.61)	10.6 (± 5.42)	9.7 (± 3.94)	
TB, Day 57, n=12, 13, 12	9.7 (± 4.25)	9.4 (± 5.84)	10.3 (± 4.9)	
TB, Day 85, n=11, 12, 12	10.4 (± 4.13)	10.3 (± 8.55)	9.2 (± 3.86)	
TB, Day 120, n=11, 13, 12	9.9 (± 4.87)	11.1 (± 7.86)	10.3 (± 3.52)	
TB, Day 165, n=12, 12, 12	12.3 (± 5.12)	12.4 (± 10.08)	9.6 (± 4.17)	
TB, follow-up, n=12, 11, 12	10.5 (± 3.9)	9.7 (± 5.88)	11.4 (± 5.37)	
DB, Screening, n=12, 13, 12	2.3 (± 1.14)	2.4 (± 1.39)	2.5 (± 1.09)	
DB, Day 1: pre-dose, n=12, 12, 12	2.2 (± 0.94)	2.2 (± 1.47)	2.3 (± 1.07)	
DB, Day 1: 4 hr, n=11, 12 ,11	2.3 (± 1.1)	2.3 (± 0.97)	2.4 (± 1.12)	
DB, Day 4, n=11, 13, 11	2.1 (± 0.7)	2.5 (± 1.33)	2.4 (± 1.12)	
DB, Day 9, n=12, 13, 12	2.3 (± 1.14)	2.5 (± 1.33)	2.5 (± 1.45)	
DB, Day 14, n=12, 13, 12	2.2 (± 1.03)	1.8 (± 1.07)	2.3 (± 0.89)	
DB, Day 21, n=12, 13, 12	2.1 (± 1.08)	2.3 (± 1.11)	1.9 (± 0.79)	
DB, Day 29: pre-dose, n=11, 13, 12	2.3 (± 1.01)	2 (± 1.29)	1.6 (± 0.79)	
DB, Day 29: 4 hr, n=12, 10 ,11	1.8 (± 0.83)	2.5 (± 0.97)	1.8 (± 0.98)	
DB, Day 32, n=11, 13, 12	2.4 (± 1.03)	2.1 (± 0.95)	2.1 (± 0.9)	
DB, Day 42, n=12, 13, 12	1.9 (± 0.79)	2.4 (± 1.19)	2.1 (± 0.79)	
DB, Day 57, n=12, 13, 12	1.8 (± 0.97)	1.9 (± 1.04)	2.2 (± 0.94)	
DB, Day 85, n=11, 12, 12	2.1 (± 0.83)	1.9 (± 1.44)	1.9 (± 1)	
DB, Day 120, n=11, 13, 12	2.1 (± 1.22)	2.3 (± 1.44)	2.2 (± 0.94)	
DB, Day 165, n=12, 12, 12	2.2 (± 1.19)	2.3 (± 1.72)	2.2 (± 1.19)	
DB, follow-up, n=12, 12, 12	2.2 (± 0.94)	1.8 (± 1.14)	2.5 (± 1.45)	
Uric acid, Screening, n=12, 13, 12	383.4 (± 90.22)	343.2 (± 45.25)	403.7 (± 141.38)	
Uric acid, Day 1: pre-dose, n=12, 12, 12	354.6 (± 69.19)	317.3 (± 48.27)	367.3 (± 115.15)	
Uric acid, Day 1: 4 hr, n=11, 12, 11	345.1 (± 76.77)	337.1 (± 44.8)	374.6 (± 113.7)	
Uric acid, Day 4, n=11, 13, 11	378.9 (± 73.68)	339.2 (± 53.7)	342.5 (± 70.47)	
Uric acid, Day 9, n=12, 13, 12	394.8 (± 72.25)	327.5 (± 54.67)	362.1 (± 113.01)	
Uric acid, Day 14, n=12, 13, 12	371.5 (± 73.76)	329.7 (± 38.12)	359.3 (± 106.74)	
Uric acid, Day 21, n=12, 13,12	377.4 (± 86.41)	349.4 (± 51.24)	369.9 (± 96.93)	
Uric acid, Day 29: pre-dose, n=11, 13, 12	373.8 (± 73.15)	318.2 (± 65.52)	351.3 (± 71.56)	

Uric acid, Day 29: 4 hr, n=12, 10, 11	377.7 (± 70.13)	335.2 (± 72.78)	369.2 (± 74.77)	
Uric acid, Day 32, n=11, 13, 12	363.9 (± 61.45)	338.5 (± 49.29)	360 (± 98.91)	
Uric acid, Day 42, n=12, 13,1 2	360.3 (± 66.93)	339.1 (± 49.42)	375.1 (± 107.18)	
Uric acid, Day 57, n=12, 13, 12	378.5 (± 70.18)	342.3 (± 72.58)	368.2 (± 97.41)	
Uric acid, Day 85, n=11, 12, 12	389.6 (± 75.62)	360.3 (± 57.89)	382.2 (± 86.89)	
Uric acid, Day 120, n=11, 13, 12	387.1 (± 73.72)	348.7 (± 60.3)	408.2 (± 133.75)	
Uric acid, Day 165, n=12, 12, 12	389.3 (± 92.6)	336 (± 52.75)	388.9 (± 118.78)	
Uric acid, follow-up, n=12, 12, 12,	375.3 (± 69.54)	351.7 (± 58.99)	400.3 (± 96.21)	
Creatinine, Screening, n=12, 13, 12	79.25 (± 12.629)	66.7 (± 22.865)	84.45 (± 36.172)	
Creatinine, Day 1: pre-dose, n=12, 12, 12	72.76 (± 9.329)	58.76 (± 21.306)	74.5 (± 29.48)	
Creatinine, Day 1: 4 hr, n=11, 12, 11	73.75 (± 13.953)	70.83 (± 20.913)	86.65 (± 36.271)	
Creatinine, Day 4, n=11, 13, 11	80.42 (± 13.807)	65.68 (± 21.55)	73.27 (± 23.152)	
Creatinine, Day 9, n=12, 13, 12	78.53 (± 9.959)	67.18 (± 27.883)	81.54 (± 38.35)	
Creatinine, Day 14, n=12, 13, 12	78.38 (± 8.858)	68.25 (± 22.215)	76.5 (± 30.091)	
Creatinine, Day 21, n=12, 13, 12	78.79 (± 11.323)	67.54 (± 23.637)	76.13 (± 23.563)	
Creatinine, Day 29: pre-dose, n=11, 13 12	75.26 (± 14.326)	63.05 (± 23.346)	70.58 (± 18.802)	
Creatinine, Day 29: 4 hr, n=12, 10, 11	80.6 (± 11.768)	64.69 (± 13.575)	83.14 (± 24.275)	
Creatinine, Day 32, n=11, 13, 12	78.19 (± 13.893)	69.72 (± 21.132)	73.79 (± 23.517)	
Creatinine, Day 42, n=12, 13, 12	79.58 (± 11.309)	67.9 (± 21.074)	76.68 (± 21.286)	
Creatinine, Day 57, n=12, 13, 12	79.43 (± 12.603)	62.82 (± 21.557)	72.2 (± 20.543)	
Creatinine, Day 85, n=12, 12, 12	77.98 (± 9.552)	65.96 (± 23.705)	73.3 (± 19.516)	
Creatinine, Day 120, n=11, 13, 12	81.96 (± 11.361)	68.87 (± 22.896)	77.58 (± 20.079)	
Creatinine, Day 165, n=12, 12, 12	83.46 (± 10.87)	71.09 (± 31.678)	76.02 (± 19.963)	
Creatinine, follow-up, n=12, 12, 12	82.77 (± 11.985)	72.35 (± 29.601)	80.14 (± 22.997)	

Notes:

[16] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[17] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[18] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Potassium, glucose, calcium, cholesterol, HDL, LDL, chloride, creatinine, sodium, triglycerides, and urea/BUN values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and

165; and FU	
End point title	Potassium, glucose, calcium, cholesterol, HDL, LDL, chloride, creatinine, sodium, triglycerides, and urea/BUN values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and FU

End point description:

Potassium, glucose, calcium, cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, chloride, creatinine, sodium, triglycerides, and urea/BUN values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[19]	13[20]	12[21]	
Units: Millimoles/liter (mmol/L)				
arithmetic mean (standard deviation)				
Potassium, Screening, n=12, 13, 12	4.41 (± 0.494)	4.32 (± 0.377)	4.37 (± 0.41)	
Potassium, Day 1: pre-dose, n=12, 12, 12	4.3 (± 0.349)	4.27 (± 0.331)	4.28 (± 0.351)	
Potassium, Day 1: 4 hr, n= 11, 12, 11	4 (± 0.654)	4.18 (± 0.374)	4.42 (± 0.506)	
Potassium, Day 4, n=11, 13, 11	4.35 (± 0.281)	4.42 (± 0.637)	4.46 (± 0.266)	
Potassium, Day 9, n=12, 13,12	4.37 (± 0.308)	4.28 (± 0.359)	4.54 (± 0.37)	
Potassium, Day 14, n=12, 13, 12	4.51 (± 0.468)	4.5 (± 0.497)	4.66 (± 0.613)	
Potassium, Day 21, n=12, 13, 12	4.42 (± 0.371)	4.51 (± 0.388)	4.56 (± 0.466)	
Potassium, Day 29: pre-dose, n=11, 13, 12	4.27 (± 0.561)	4.19 (± 0.366)	4.3 (± 0.388)	
Potassium, Day 29: 4 hr, n=12, 10, 11	4.32 (± 0.6)	4 (± 0.478)	4.25 (± 0.468)	
Potassium, Day 32, n=11, 13, 12	4.48 (± 0.343)	4.59 (± 0.689)	4.51 (± 0.442)	
Potassium, Day 42, n=12, 13, 12	4.51 (± 0.219)	4.48 (± 0.511)	4.66 (± 0.558)	
Potassium, Day 57, n=12, 13, 12	4.48 (± 0.515)	4.28 (± 0.277)	4.25 (± 0.355)	
Potassium, Day 85, n=11, 12, 12	4.37 (± 0.358)	4.4 (± 0.451)	4.38 (± 0.51)	
Potassium, Day 120, n=11, 13, 12	4.51 (± 0.308)	4.56 (± 0.686)	4.4 (± 0.437)	
Potassium, Day 165, n=12, 12, 11	4.52 (± 0.609)	4.38 (± 0.411)	4.19 (± 0.532)	
Potassium, follow-up, n=12, 12, 12	4.5 (± 0.499)	4.42 (± 0.465)	4.52 (± 0.371)	
Glucose, Day 1: pre-dose, n=12, 13, 12	10.04 (± 2.545)	8.64 (± 1.532)	9.26 (± 1.89)	
Glucose, Day 1: 4 hr, n= 12, 13, 12	12.45 (± 4.058)	9.33 (± 1.7)	11.65 (± 3.087)	
Glucose, Day 4, n=11, 13, 11	9.91 (± 2.117)	8.41 (± 1.317)	9.33 (± 1.939)	
Glucose, Day 9, n=12, 13, 12	9.72 (± 1.799)	8.32 (± 1.445)	9.08 (± 1.173)	
Glucose, Day 14, n=11, 13, 12	9.76 (± 1.691)	8.7 (± 1.942)	8.88 (± 1.633)	
Glucose, Day 21, n=12, 13, 12	9.77 (± 1.308)	8.86 (± 2.042)	9.08 (± 1.904)	
Glucose, Day 29: pre-dose, n=12, 13, 12	9.76 (± 1.898)	8.37 (± 1.758)	9.22 (± 1.736)	
Glucose, Day 29: 4 hr, n=12, 13, 12	11.55 (± 3.987)	10.01 (± 2.761)	10.73 (± 2.776)	
Glucose, Day 32, n=12, 13, 12	9.58 (± 1.436)	8.64 (± 1.877)	9.15 (± 1.868)	

Glucose, Day 42, n=12, 13, 12	9.84 (± 1.829)	8.22 (± 1.438)	9.68 (± 3.568)	
Glucose, Day 57, n=12, 13, 12	9.05 (± 1.652)	8.43 (± 1.849)	8.13 (± 1.659)	
Glucose, Day 85, n=12, 13, 12	9.25 (± 1.71)	8.82 (± 2.127)	8.68 (± 2.146)	
Glucose, Day 120, n=11, 13, 12	8.73 (± 1.716)	9.62 (± 2.533)	9.01 (± 1.714)	
Glucose, Day 165, n=12, 13, 12	8.84 (± 1.388)	8.98 (± 2.318)	8.94 (± 1.713)	
Glucose, follow-up, n=12, 13, 12	9.81 (± 2.475)	8.67 (± 2.322)	9.55 (± 3.499)	
Calcium, Screening, n=12, 13, 12	2.467 (± 0.0931)	2.445 (± 0.0723)	2.416 (± 0.0742)	
Calcium, Day 1: pre-dose, n=12, 12, 12	2.35 (± 0.1681)	2.361 (± 0.1423)	2.405 (± 0.0888)	
Calcium, Day 1: 4 hr, n= 11, 12, 11	2.322 (± 0.2997)	2.4 (± 0.1135)	2.401 (± 0.1018)	
Calcium, Day 4, n=11, 13, 11	2.45 (± 0.0647)	2.382 (± 0.0941)	2.424 (± 0.1083)	
Calcium, Day 9, n=12, 13, 12	2.473 (± 0.0913)	2.406 (± 0.0749)	2.428 (± 0.1194)	
Calcium, Day 14, n=12, 13, 12	2.465 (± 0.0657)	2.396 (± 0.0947)	2.341 (± 0.1847)	
Calcium, Day 21, n=12, 13, 12	2.453 (± 0.0729)	2.423 (± 0.0774)	2.377 (± 0.0986)	
Calcium, Day 29: pre-dose, n=11, 13,12	2.394 (± 0.2223)	2.335 (± 0.1815)	2.392 (± 0.079)	
Calcium, Day 29: 4 hr, n=12, 10, 11	2.351 (± 0.2092)	2.301 (± 0.2548)	2.355 (± 0.1026)	
Calcium, Day 32, n=11, 13, 12	2.425 (± 0.0505)	2.392 (± 0.1129)	2.399 (± 0.0762)	
Calcium, Day 42, n=12, 13, 12	2.456 (± 0.0784)	2.404 (± 0.0636)	2.397 (± 0.1367)	
Calcium, Day 57, n=12, 13, 12	2.411 (± 0.1108)	2.319 (± 0.1689)	2.383 (± 0.1041)	
Calcium, Day 85, n=11, 12, 12	2.455 (± 0.0792)	2.413 (± 0.1013)	2.423 (± 0.1314)	
Calcium, Day 120, n=11, 13, 12	2.448 (± 0.1002)	2.365 (± 0.1761)	2.407 (± 0.0579)	
Calcium, Day 165, n=12, 12, 11	2.459 (± 0.1145)	2.426 (± 0.0915)	2.396 (± 0.1068)	
Calcium, follow-up, n=12, 11, 12	2.453 (± 0.0758)	2.37 (± 0.0952)	2.412 (± 0.0992)	
Cholesterol, Screening, n=12, 13, 12	4.691 (± 0.9451)	4.616 (± 0.9833)	4.93 (± 1.135)	
Cholesterol, Day 1: pre-dose, n= 12, 12, 12	4.445 (± 0.7338)	4.442 (± 1.0774)	4.501 (± 1.2156)	
Cholesterol, Day 1: 4 hr, n=11, 12, 11	4.189 (± 0.8437)	4.361 (± 0.7929)	4.307 (± 1.2554)	
Cholesterol, Day 4, n=11, 13, 11	4.489 (± 0.7969)	4.465 (± 0.9046)	4.38 (± 1.2766)	
Cholesterol, Day 9, n=12, 13, 12	4.454 (± 0.8224)	4.365 (± 0.8639)	4.325 (± 1.1791)	
Cholesterol, Day 14, n=12, 13, 12	4.428 (± 0.9009)	4.37 (± 0.875)	4.4 (± 1.1531)	
Cholesterol, Day 21, n=12, 13, 12	4.434 (± 0.9178)	4.528 (± 0.8273)	4.452 (± 1.2251)	
Cholesterol, Day 29: pre-dose, n=11, 13, 12	4.221 (± 0.8373)	4.281 (± 1.0434)	4.562 (± 1.0764)	
Cholesterol, Day 29: 4 hr, n=12, 10, 11	4.236 (± 0.9041)	4.009 (± 0.8938)	4.265 (± 1.1512)	
Cholesterol, Day 32, n=11, 13, 12	4.542 (± 0.8357)	4.305 (± 0.8342)	4.462 (± 1.0283)	
Cholesterol, Day 42, n=12, 13, 12	4.698 (± 0.6961)	4.312 (± 0.7405)	4.531 (± 1.1809)	

Cholesterol, Day 57, n=12, 13, 12	4.785 (± 1.0829)	4.292 (± 0.829)	4.763 (± 1.5079)	
Cholesterol, Day 85, n=11, 12, 12	4.936 (± 1.2475)	4.582 (± 0.9766)	4.585 (± 1.2112)	
Cholesterol, Day 120, n=11, 13, 12	4.56 (± 0.9324)	4.364 (± 1.0527)	4.778 (± 1.2748)	
Cholesterol, Day 165, n=12, 12, 12	4.691 (± 1.0977)	4.345 (± 0.7629)	4.748 (± 1.0543)	
Cholesterol, follow-up, n=12, 12, 12	4.944 (± 1.1249)	4.64 (± 0.8404)	4.32 (± 1.2699)	
HCD, Screening, n=12, 13, 12	1.038 (± 0.2031)	1.068 (± 0.2076)	1.103 (± 0.3764)	
HCD, Day 1: pre-dose, n=12, 12, 12	0.987 (± 0.1997)	1.021 (± 0.1821)	1.028 (± 0.3983)	
HCD, Day 1: 4 hr, n= 11, 12, 11	0.882 (± 0.2371)	0.905 (± 0.1766)	0.908 (± 0.3601)	
HCD, Day 4, n=11, 13, 11	1.016 (± 0.1767)	1.018 (± 0.1763)	1.059 (± 0.4174)	
HCD, Day 9, n=12, 13, 12	1.044 (± 0.2095)	1.052 (± 0.2055)	1.092 (± 0.4131)	
HCD, Day 14, n=12, 13, 12	1.031 (± 0.2288)	1.058 (± 0.231)	1.128 (± 0.4724)	
HCD, Day 21, n=12, 13, 12	1.059 (± 0.2206)	1.086 (± 0.2239)	1.15 (± 0.5763)	
HCD, Day 29: pre-dose, n=11, 13,12	0.979 (± 0.2402)	1.035 (± 0.1966)	1.144 (± 0.5198)	
HCD, Day 29: 4 hr, n=12, 10, 11	0.89 (± 0.1842)	0.945 (± 0.2067)	1.035 (± 0.5248)	
HCD, Day 32, n=11, 13, 12	1.056 (± 0.2792)	1.049 (± 0.2238)	1.128 (± 0.4264)	
HCD, Day 42, n=12, 13, 12	1.05 (± 0.2429)	1.061 (± 0.2222)	1.147 (± 0.4933)	
HCD, Day 57, n=12, 13, 12	1.008 (± 0.2057)	1.066 (± 0.2412)	1.143 (± 0.4881)	
HCD, Day 85, n=11, 12, 12	1.034 (± 0.2695)	1.071 (± 0.2734)	1.147 (± 0.4588)	
HCD, Day 120, n=11, 13, 12	1.043 (± 0.2749)	1.111 (± 0.3225)	1.143 (± 0.4692)	
HCD, Day 165, n=12, 12, 12	1.04 (± 0.2663)	1.123 (± 0.2947)	1.115 (± 0.3964)	
HCD, follow-up, n=12, 12, 12	1.118 (± 0.2713)	1.103 (± 0.2074)	1.101 (± 0.4437)	
LCC, Screening, n=12, 13, 12	2.554 (± 0.808)	2.669 (± 0.8961)	2.937 (± 1.131)	
LCC, Day 1: pre-dose, n=12, 12, 12	2.361 (± 0.8784)	2.624 (± 0.9658)	2.564 (± 1.1659)	
LCC, Day 1: 4 hr, n=11, 12, 10	1.907 (± 0.7812)	2.228 (± 0.7441)	2.228 (± 1.1966)	
LCC, Day 4, n=11, 13, 11	2.373 (± 0.8578)	2.684 (± 0.8231)	2.605 (± 1.2231)	
LCC, Day 9, n=12, 13, 12	2.304 (± 0.7187)	2.523 (± 0.8824)	2.449 (± 1.1501)	
LCC, Day 14, n=12, 13, 12	2.273 (± 0.7569)	2.497 (± 0.7612)	2.484 (± 1.0383)	
LCC, Day 21, n=12, 13, 12	2.346 (± 0.9068)	2.577 (± 0.8484)	2.468 (± 0.9989)	
LCC, Day 29: pre-dose, n=11, 13, 12	2.185 (± 0.8694)	2.522 (± 1.0284)	2.521 (± 0.9772)	
LCC, Day 29: 4 hr, n=12, 10, 11	1.998 (± 0.8793)	2.067 (± 0.8523)	2.105 (± 1.0604)	
LCC, Day 32, n=11, 13, 12	2.482 (± 0.6992)	2.45 (± 0.7498)	2.583 (± 0.9974)	

LCC, Day 42, n=11, 13, 12	2.693 (± 0.6449)	2.505 (± 0.7698)	2.563 (± 1.0248)	
LCC, Day 57, n=12, 13, 12	2.587 (± 1.0039)	2.474 (± 0.8736)	2.693 (± 1.3943)	
LCC, Day 85, n=11, 12, 12	2.738 (± 1.1679)	2.598 (± 0.885)	2.587 (± 1.1567)	
LCC, Day 120, n=10, 13, 12	2.591 (± 0.8264)	2.435 (± 0.9239)	2.639 (± 1.138)	
LCC, Day 165, n=12, 12, 12	2.556 (± 1.2146)	2.453 (± 0.6825)	2.718 (± 1.119)	
LCC, follow-up, n=12, 12, 12	2.672 (± 1.224)	2.736 (± 0.7792)	2.366 (± 1.2395)	
Chloride, Screening, n=12, 13, 12	103.6 (± 2.39)	101.7 (± 2.98)	103.1 (± 3.45)	
Chloride, Day 1: pre-dose, n=12, 12, 12	104.2 (± 2.92)	103.2 (± 3.71)	103.2 (± 3.59)	
Chloride, Day 1: 4 hr, n= 11, 12, 11	103.3 (± 5.14)	101.8 (± 3.16)	102.7 (± 3.38)	
Chloride, Day 4, n=11, 13, 11	102.3 (± 3.13)	102.1 (± 2.5)	103.9 (± 4.44)	
Chloride, Day 9, n=12, 13, 12	102.8 (± 1.82)	102 (± 2.24)	103.9 (± 3.15)	
Chloride, Day 14, n=12, 13, 12	102.1 (± 2.5)	102.8 (± 3.05)	103.7 (± 4.23)	
Chloride, Day 21, n=12, 13, 12	103.2 (± 2.59)	102.2 (± 3.48)	104 (± 2.76)	
Chloride, Day 29: pre-dose, n=11, 13, 12	104.5 (± 3.21)	103.2 (± 1.86)	103.2 (± 3.24)	
Chloride, Day 29: 4 hr, n=12, 10, 11	102.6 (± 4.21)	103.2 (± 5.12)	103.9 (± 2.84)	
Chloride, Day 32, n=11, 13, 12	103.5 (± 3.24)	102.4 (± 2.53)	103.7 (± 3.45)	
Chloride, Day 42, n=12, 13, 12	102.8 (± 2.34)	102.7 (± 2.98)	102.8 (± 2.59)	
Chloride, Day 57, n=12, 13, 12	103.4 (± 1.83)	104.1 (± 3.95)	104.1 (± 3)	
Chloride, Day 85, n=11, 12, 12	103.5 (± 2.88)	102.7 (± 2.57)	103.8 (± 3.44)	
Chloride, Day 120, n=11, 13, 12	102.8 (± 1.94)	102.5 (± 2.88)	103 (± 3.19)	
Chloride, Day 165, n=12, 12,1 2	103.3 (± 2.34)	103.1 (± 2.94)	102.7 (± 3.65)	
Chloride, follow-up, n=12, 12,12	103.3 (± 2.53)	102.1 (± 2.91)	103.4 (± 3.37)	
Sodium, Screening, n=12, 13, 12	140.3 (± 1.96)	138.5 (± 2.15)	138.8 (± 1.19)	
Sodium, Day 1: pre-dose, n=12, 12, 12	139.4 (± 2.15)	138.5 (± 3.03)	139.2 (± 1.47)	
Sodium, Day 1: 4 hr, n=11, 12, 11	138 (± 2.83)	138.3 (± 2.38)	137.7 (± 1.9)	
Sodium, Day 4, n=11, 13, 11	138.9 (± 2.07)	139.3 (± 2.36)	139.2 (± 1.89)	
Sodium, Day 9, n=12, 13, 12	138.8 (± 2.04)	138 (± 1.78)	139.3 (± 1.54)	
Sodium, Day 14, n=12, 13, 12	139.5 (± 1.17)	139.6 (± 2.43)	139.9 (± 2.19)	
Sodium, Day 21, n=12, 13, 12	139.3 (± 1.61)	138.5 (± 2.37)	139.7 (± 1.56)	
Sodium, Day 29: pre-dose, n=11, 13, 12	139.5 (± 1.69)	138.5 (± 1.9)	139.2 (± 2.29)	
Sodium, Day 29: 4 hr, n=12, 10, 11	137.9 (± 2.87)	139.2 (± 3.08)	138.1 (± 1.58)	
Sodium, Day 32, n=11, 13, 12	139.6 (± 1.69)	139.5 (± 2.07)	139 (± 1.71)	
Sodium, Day 42, n=12, 13, 12	139.2 (± 2.29)	139.2 (± 1.77)	138.5 (± 1.78)	
Sodium, Day 57, n=12, 13, 12	140.1 (± 1.73)	138.5 (± 2.54)	140.1 (± 1.98)	
Sodium, Day 85, n=11, 12, 12	139.1 (± 2.21)	138.5 (± 1.45)	139.4 (± 1.38)	
Sodium, Day 120, n=11, 13, 12	139.4 (± 2.2)	138.7 (± 3.2)	139.6 (± 1.38)	
Sodium, Day 165, n=12, 12, 12	139.3 (± 1.48)	138.6 (± 2.61)	138.4 (± 1.38)	
Sodium, follow-up, n=12, 12, 12	139.7 (± 1.97)	139.1 (± 2.39)	139.5 (± 2.68)	
Triglyceride, Screening, n=12, 13, 12	2.398 (± 0.9159)	1.915 (± 0.8348)	1.941 (± 0.6399)	
Triglyceride, Day 1: pre-dose, n=12, 12, 12	2.394 (± 0.802)	1.736 (± 0.8439)	1.988 (± 0.7275)	
Triglyceride, Day 1: 4 hr, n=11, 12, 11	3.055 (± 0.6153)	2.676 (± 0.9959)	2.575 (± 1.0535)	
Triglyceride, Day 4, n=11, 13, 11	2.396 (± 1.1058)	1.663 (± 0.6341)	1.554 (± 0.4501)	
Triglyceride, Day 9, n=12, 13, 12	2.41 (± 0.7973)	1.722 (± 0.8948)	1.707 (± 0.8005)	

Triglyceride, Day 14, n=12, 13, 12	2.448 (± 0.8671)	1.774 (± 0.8668)	1.718 (± 0.6216)	
Triglyceride, Day 21, n=12, 13, 12	2.243 (± 0.739)	1.887 (± 0.8812)	1.818 (± 0.8204)	
Triglyceride, Day 29: pre-dose, n=11, 13, 12	2.305 (± 0.785)	1.582 (± 0.7214)	1.953 (± 0.733)	
Triglyceride, Day 29: 4 hr, n=12, 10, 11	2.941 (± 0.5848)	2.172 (± 1.0823)	2.454 (± 0.8392)	
Triglyceride, Day 32, n=11, 13, 12	2.186 (± 0.8153)	1.755 (± 0.8522)	1.64 (± 0.4573)	
Triglyceride, Day 42, n=12, 13, 12	2.598 (± 1.5567)	1.625 (± 0.5765)	1.787 (± 0.5062)	
Triglyceride, Day 57, n=12, 13, 12	2.597 (± 0.8576)	1.642 (± 0.687)	2.019 (± 0.7403)	
Triglyceride, Day 85, n=11, 12, 12	2.54 (± 0.8901)	1.987 (± 0.6512)	1.856 (± 0.5816)	
Triglyceride, Day 120, n=11, 13, 12	2.522 (± 1.4038)	1.785 (± 1.012)	2.174 (± 0.6871)	
Triglyceride, Day 165, n=12, 12, 12	2.387 (± 1.0518)	1.675 (± 0.866)	1.998 (± 0.7234)	
Triglyceride, follow-up, n=12, 12, 12	2.516 (± 1.0983)	1.748 (± 0.7628)	1.858 (± 0.6771)	
Urea/BUN, Screening, n=12, 13, 12	7.56 (± 2.65)	5.52 (± 1.357)	6.15 (± 2.388)	
Urea/BUN, Day 1: pre-dose, n=12, 12, 12	6.33 (± 1.866)	5.53 (± 1.281)	6.76 (± 4.384)	
Urea/BUN, Day 1: 4 hr, n=11, 12, 11	6.3 (± 1.581)	6.01 (± 1.178)	7.32 (± 4.064)	
Urea/BUN, Day 4, n=11, 13, 11	6.76 (± 1.397)	5.75 (± 0.759)	6.58 (± 2.923)	
Urea/BUN, Day 9, n=12, 13, 12	6.41 (± 1.005)	5.35 (± 1.087)	6.98 (± 3.595)	
Urea/BUN, Day 14, n=12, 13, 12	6.48 (± 1.434)	5.99 (± 1.495)	6.7 (± 3.821)	
Urea/BUN, Day 21, n=12, 13, 12	6.86 (± 1.685)	5.75 (± 1.222)	6.36 (± 1.846)	
Urea/BUN, Day 29: pre-dose, n=11, 13, 12	6.97 (± 2.039)	5.54 (± 1.309)	5.85 (± 1.633)	
Urea/BUN, Day 29: 4 hr, n=12, 10, 11	7.13 (± 1.697)	5.73 (± 0.906)	6.55 (± 1.929)	
Urea/BUN, Day 32, n=11, 13, 12	6.86 (± 1.604)	5.78 (± 1.118)	6.38 (± 2.173)	
Urea/BUN, Day 42, n=12, 13, 12	6.53 (± 1.224)	5.67 (± 1.005)	6.4 (± 1.744)	
Urea/BUN, Day 57, n=12, 13, 12	6.68 (± 1.805)	5.65 (± 1.335)	6.27 (± 2.163)	
Urea/BUN, Day 85, n=11, 12, 12	6.72 (± 1.211)	5.76 (± 1.835)	6.33 (± 2.106)	
Urea/BUN, Day 120, n=11, 13, 12	7.46 (± 1.751)	5.92 (± 1.101)	6.19 (± 1.771)	
Urea/BUN, Day 165, n=12, 12, 12	6.93 (± 2.355)	6.03 (± 1.463)	6.25 (± 2.058)	
Urea/BUN, follow-up, n=12, 12, 12	7.04 (± 1.929)	6.03 (± 1.069)	6.38 (± 2.086)	

Notes:

[19] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[20] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[21] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Total cholesterol/HDL ratio (TC/HDL ratio), HDL/LDL ratio, and triglyceride/HDL ratio (TG/HDL ratio) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Total cholesterol/HDL ratio (TC/HDL ratio), HDL/LDL ratio, and triglyceride/HDL ratio (TG/HDL ratio) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

TC/HDL ratio, HDL/LDL ratio, and triglyceride/HDL ratio values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[22]	13[23]	12[24]	
Units: Ratio				
arithmetic mean (standard deviation)				
TC/HDL ratio, Screening, n=12, 13, 12	4.5517 (± 0.67139)	4.4335 (± 1.16277)	4.8275 (± 1.61827)	
TC/HDL ratio, Day 1: pre-dose, n=12, 12, 12	4.5833 (± 0.75575)	4.4437 (± 1.3486)	4.8528 (± 1.98221)	
TC/HDL ratio, Day 1: 4 hr, n= 11, 12, 11	4.8928 (± 0.95411)	4.9908 (± 1.40456)	5.2906 (± 2.31631)	
TC/HDL ratio, Day 4, n=11, 13, 11	4.4785 (± 0.79579)	4.4726 (± 1.16211)	4.539 (± 1.81475)	
TC/HDL ratio, Day 9, n=12, 13, 12	4.3908 (± 1.05287)	4.2825 (± 1.21595)	4.3225 (± 1.66246)	
TC/HDL ratio, Day 14, n=12, 13, 12	4.3954 (± 0.93858)	4.266 (± 1.16649)	4.2618 (± 1.56118)	
TC/HDL ratio, Day 21, n=12, 13, 12	4.264 (± 0.81159)	4.3206 (± 1.22274)	4.3941 (± 1.90723)	
TC/HDL ratio, Day 29: pre-dose, n=11, 13, 12	4.3882 (± 0.73541)	4.2708 (± 1.36303)	4.544 (± 2.02278)	
TC/HDL ratio, Day 29: 4 hr, n=12, 10, 11	4.8172 (± 0.92837)	4.4191 (± 1.45277)	4.7201 (± 2.12839)	
TC/HDL ratio, Day 32, n=11, 13, 12	4.4461 (± 0.87461)	4.3118 (± 1.51533)	4.323 (± 1.6147)	
TC/HDL ratio, Day 42, n=12, 13, 12	4.6364 (± 1.06085)	4.2224 (± 1.14198)	4.3167 (± 1.59367)	
TC/HDL ratio, Day 57, n=12, 13, 12	4.8836 (± 1.42324)	4.221 (± 1.29056)	4.5542 (± 1.97068)	
TC/HDL ratio, Day 85, n=11, 12, 12	4.97 (± 1.58565)	4.5079 (± 1.43704)	4.421 (± 1.9158)	
TC/HDL ratio, Day 120, n=11, 13, 12	4.4824 (± 0.67007)	4.2153 (± 1.71395)	4.6894 (± 2.096)	
TC/HDL ratio, Day 165, n=12, 12, 12	4.6683 (± 1.2241)	4.1097 (± 1.38627)	4.7094 (± 1.87947)	
TC/HDL ratio, follow-up, n=12, 12, 12	4.5717 (± 1.11481)	4.3414 (± 1.13258)	4.258 (± 1.43006)	
HDL/LDL ratio, Screening, n=12, 13, 12	0.4322 (± 0.11034)	0.4349 (± 0.14208)	0.4299 (± 0.21361)	
HDL/LDL ratio, Day 1: pre-dose, n=12, 12, 12	0.489 (± 0.2366)	0.4271 (± 0.13)	0.4816 (± 0.28547)	
HDL/LDL ratio, Day 1: 4 hr, n=11, 12, 10	0.571 (± 0.31912)	0.4393 (± 0.12977)	0.5166 (± 0.29093)	
HDL/LDL ratio, Day 4, n=11, 13, 11	0.4904 (± 0.2106)	0.409 (± 0.12033)	0.4879 (± 0.27487)	
HDL/LDL ratio, Day 9, n=12, 13, 12	0.4962 (± 0.1882)	0.4571 (± 0.15287)	0.5602 (± 0.33874)	

HDL/LDL ratio, Day 14, n=12, 13, 12	0.4958 (± 0.18073)	0.4536 (± 0.13598)	0.5247 (± 0.2519)	
HDL/LDL ratio, Day 21, n=12, 13, 12	0.5028 (± 0.17479)	0.4568 (± 0.14559)	0.5263 (± 0.2703)	
HDL/LDL ratio, Day 29: pre-dose, n=11, 13, 12	0.5429 (± 0.29396)	0.4583 (± 0.15254)	0.5254 (± 0.32512)	
HDL/LDL ratio, Day 29: 4 hr, n=11, 10, 11	0.569 (± 0.33723)	0.511 (± 0.17463)	0.5969 (± 0.32829)	
HDL/LDL ratio, Day 32, n=11, 13, 12	0.4463 (± 0.12702)	0.4682 (± 0.16788)	0.5001 (± 0.25773)	
HDL/LDL ratio, Day 42, n=11, 13, 12	0.4219 (± 0.14536)	0.4587 (± 0.15812)	0.5164 (± 0.25657)	
HDL/LDL ratio, Day 57, n=12, 13, 12	0.4418 (± 0.17798)	0.4759 (± 0.18751)	0.5732 (± 0.41531)	
HDL/LDL ratio, Day 85, n=11, 12, 12	0.4347 (± 0.17966)	0.4483 (± 0.16274)	0.5525 (± 0.38936)	
HDL/LDL ratio, Day 120, n=10, 13, 12	0.4365 (± 0.10934)	0.4966 (± 0.17561)	0.5176 (± 0.3155)	
HDL/LDL ratio, Day 165, n=12, 12, 12	0.5048 (± 0.27435)	0.4811 (± 0.15581)	0.5289 (± 0.44948)	
HDL/LDL ratio, follow-up, n=12, 12, 12	0.4963 (± 0.2287)	0.4322 (± 0.14335)	0.581 (± 0.37442)	
TG/HDL ratio, Screening, n=12, 13, 12	2.3782 (± 0.97356)	1.9368 (± 1.10017)	2.0276 (± 1.1114)	
TG/HDL ratio, Day 1: pre-dose, n=12, 12, 12	2.5398 (± 1.09229)	1.7328 (± 0.81922)	2.2982 (± 1.40144)	
TG/HDL ratio, Day 1: 4 hr, n=11, 12, 11	3.7321 (± 1.34144)	3.1181 (± 1.41296)	3.3154 (± 1.89189)	
TG/HDL ratio, Day 4, n=11, 13, 11	2.5015 (± 1.33091)	1.6556 (± 0.59018)	1.7557 (± 1.0279)	
TG/HDL ratio, Day 9, n=12, 13, 12	2.4587 (± 1.08718)	1.7316 (± 0.94072)	1.8978 (± 1.26276)	
TG/HDL ratio, Day 14, n=12, 13, 12	2.5216 (± 1.13514)	1.8014 (± 1.0782)	1.8224 (± 1.15332)	
TG/HDL ratio, Day 21, n=12, 13, 12	2.2854 (± 1.11024)	1.9121 (± 1.22395)	1.965 (± 1.25287)	
TG/HDL ratio, Day 29: pre-dose, n=11, 13, 12	2.5333 (± 1.26093)	1.6627 (± 1.04388)	2.1053 (± 1.38927)	
TG/HDL ratio, Day 29: 4 hr, n=12, 10, 11	3.4249 (± 1.02583)	2.4966 (± 1.45071)	2.8369 (± 1.54468)	
TG/HDL ratio, Day 32, n=11, 13, 12	2.2721 (± 1.07761)	1.8371 (± 1.25628)	1.6781 (± 0.79591)	
TG/HDL ratio, Day 42, n=12, 13, 12	2.7965 (± 2.27015)	1.6805 (± 0.89388)	1.8026 (± 0.87202)	
TG/HDL ratio, Day 57, n=12, 13, 12	2.7234 (± 1.12785)	1.7039 (± 1.04513)	1.9699 (± 0.99277)	
TG/HDL ratio, Day 85, n=11, 12, 12	2.7858 (± 1.62412)	2.0578 (± 1.04219)	1.827 (± 0.91655)	
TG/HDL ratio, Day 120, n=11, 13, 12	2.781 (± 2.29533)	1.9532 (± 1.78872)	2.2421 (± 1.27475)	
TG/HDL ratio, Day 165, n=12, 12, 12	2.5915 (± 1.63262)	1.7162 (± 1.37165)	2.0827 (± 1.22584)	
TG/HDL ratio, follow-up, n=12, 12, 12	2.512 (± 1.49353)	1.675 (± 0.83953)	1.9843 (± 1.18512)	

Notes:

[22] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[23] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[24] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Glomerular filtration rate (GFR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Glomerular filtration rate (GFR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

GFR values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[25]	13[26]	12[27]	
Units: mL/second/1.73 meters squared (m^2)				
arithmetic mean (standard deviation)				
GFR, Day 1: pre-dose, n=12, 12, 12	1.58511 (± 0.277574)	2.02627 (± 0.46816)	1.67696 (± 0.608263)	
GFR, Day 1: 4 hr, n= 11, 11, 11	1.59561 (± 0.4595)	1.63205 (± 0.416637)	1.40432 (± 0.491131)	
GFR, Day 4, n=11, 13, 11	1.41343 (± 0.288603)	1.78818 (± 0.405897)	1.63053 (± 0.503625)	
GFR, Day 9, n=12, 13, 12	1.44594 (± 0.226133)	1.79975 (± 0.455115)	1.54058 (± 0.531265)	
GFR, Day 14, n=12, 13, 12	1.44316 (± 0.21988)	1.71753 (± 0.436966)	1.60877 (± 0.538198)	
GFR, Day 21, n=12, 13, 12	1.44316 (± 0.226469)	1.75093 (± 0.429564)	1.54893 (± 0.430925)	
GFR, Day 29: pre-dose, n=11, 13, 12	1.54551 (± 0.347694)	1.90508 (± 0.475019)	1.66443 (± 0.455756)	
GFR, Day 29: 4 hr, n=12, 9, 11	1.4195 (± 0.295839)	1.66258 (± 0.314443)	1.37395 (± 0.359659)	
GFR, Day 32, n=11, 13, 12	1.46353 (± 0.280965)	1.65844 (± 0.379313)	1.62547 (± 0.509746)	
GFR, Day 42, n=12, 13, 12	1.42646 (± 0.227363)	1.71239 (± 0.37693)	1.5197 (± 0.443158)	
GFR, Day 57, n=12, 13, 12	1.44316 (± 0.280753)	1.89481 (± 0.491664)	1.63799 (± 0.479404)	
GFR, Day 85, n=12, 12, 12	1.45568 (± 0.227182)	1.78551 (± 0.428052)	1.59068 (± 0.427914)	
GFR, Day 120, n=11, 13, 12	1.36636 (± 0.231621)	1.70725 (± 0.44379)	1.48491 (± 0.390837)	
GFR, Day 165, n=12, 12, 12	1.34157 (± 0.158323)	1.77855 (± 0.601052)	1.52527 (± 0.417065)	
GFR, follow-up, n=12, 12, 12	1.35966 (± 0.219071)	1.71036 (± 0.533234)	1.46821 (± 0.4867)	

Notes:

[25] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[26] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[27] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Basophil, eosinophil, lymphocyte, monocyte, segmented neutrophil (SN), TN, platelet count, and WBC count values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Basophil, eosinophil, lymphocyte, monocyte, segmented neutrophil (SN), TN, platelet count, and WBC count values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Basophil, eosinophil, lymphocyte, monocyte, SN, total neutrophil (TN), platelet count, and white blood cell (WBC) count values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[28]	13[29]	12[30]	
Units: 10^9 cells per liter (GI/L)				
arithmetic mean (standard deviation)				
Basophils, Screening, n=12, 12, 11	0.035 (± 0.0109)	0.026 (± 0.0156)	0.024 (± 0.0121)	
Basophils, Day 1: pre-dose, n=12, 13, 11	0.031 (± 0.009)	0.028 (± 0.0109)	0.026 (± 0.0175)	
Basophils, Day 1: 4 hr, n=12, 12, 11	0.027 (± 0.0115)	0.027 (± 0.0115)	0.028 (± 0.0154)	
Basophils, Day 4, n=11, 12, 11	0.037 (± 0.0149)	0.038 (± 0.0269)	0.032 (± 0.0125)	
Basophils, Day 9, n=12, 13, 12	0.029 (± 0.0067)	0.028 (± 0.0121)	0.035 (± 0.0183)	
Basophils, Day 14, n=12, 12, 12	0.039 (± 0.0116)	0.035 (± 0.0157)	0.032 (± 0.014)	
Basophils, Day 21, n=12, 13, 12	0.036 (± 0.0151)	0.032 (± 0.0128)	0.031 (± 0.0183)	
Basophils, Day 29: pre-dose, n=12, 13, 12	0.038 (± 0.0164)	0.025 (± 0.012)	0.027 (± 0.0161)	
Basophils, Day 29: 4 hr, n=12, 13, 11	0.032 (± 0.0103)	0.028 (± 0.0215)	0.027 (± 0.0127)	
Basophils, Day 32, n=12, 13, 10	0.038 (± 0.0094)	0.026 (± 0.0119)	0.031 (± 0.0238)	

Basophils, Day 42, n=12, 13, 12	0.037 (± 0.0167)	0.026 (± 0.0145)	0.033 (± 0.0166)	
Basophils, Day 57, n=12, 13, 12	0.028 (± 0.0111)	0.025 (± 0.0105)	0.03 (± 0.0154)	
Basophils, Day 85, n=12, 13, 12	0.03 (± 0.0121)	0.025 (± 0.0156)	0.028 (± 0.0111)	
Basophils, Day 120, n=10, 13, 12	0.031 (± 0.012)	0.035 (± 0.0181)	0.031 (± 0.0151)	
Basophils, Day 165, n=12, 13, 12	0.035 (± 0.0162)	0.037 (± 0.017)	0.032 (± 0.0185)	
Basophils, follow-up, n=12, 13, 12	0.032 (± 0.0119)	0.032 (± 0.0099)	0.028 (± 0.019)	
Eosinophils, Screening, n=12, 12, 11	0.193 (± 0.1046)	0.139 (± 0.0728)	0.211 (± 0.1612)	
Eosinophils, Day 1: pre-dose, n=12, 13, 11	0.21 (± 0.1648)	0.206 (± 0.1295)	0.234 (± 0.1539)	
Eosinophils, Day 1: 4 hr, 12, 12, 11	0.157 (± 0.13)	0.216 (± 0.2164)	0.206 (± 0.1496)	
Eosinophils, Day 4, n=11, 12, 11	0.216 (± 0.1214)	0.143 (± 0.0862)	0.226 (± 0.1364)	
Eosinophils, Day 9, n=12, 13, 12	0.188 (± 0.106)	0.188 (± 0.1166)	0.288 (± 0.2169)	
Eosinophils, Day 14, n=12, 12, 12	0.228 (± 0.141)	0.185 (± 0.0834)	0.246 (± 0.1154)	
Eosinophils, Day 21, n=12, 13, 12	0.234 (± 0.1725)	0.202 (± 0.1057)	0.258 (± 0.1638)	
Eosinophils, Day 29: pre-dose, n=12, 13, 12	0.232 (± 0.218)	0.198 (± 0.1514)	0.209 (± 0.1396)	
Eosinophils, Day 29: 4 hr, n=12, 13, 11	0.205 (± 0.2068)	0.211 (± 0.1413)	0.18 (± 0.1096)	
Eosinophils, Day 32, n=12, 13, 10	0.193 (± 0.1321)	0.204 (± 0.1183)	0.254 (± 0.1767)	
Eosinophils, Day 42, n=12, 13, 12	0.219 (± 0.1439)	0.18 (± 0.124)	0.247 (± 0.1942)	
Eosinophils, Day 57, n=12, 13, 12	0.216 (± 0.1323)	0.168 (± 0.115)	0.239 (± 0.1647)	
Eosinophils, Day 85, n=12, 13, 12	0.226 (± 0.1479)	0.161 (± 0.0867)	0.242 (± 0.1591)	
Eosinophils, Day 120, n=10, 13, 12	0.252 (± 0.1578)	0.185 (± 0.126)	0.275 (± 0.2013)	
Eosinophils, Day 165, n=12, 13, 12	0.193 (± 0.124)	0.178 (± 0.1133)	0.235 (± 0.1278)	
Eosinophils, follow-up, n=12, 13, 12	0.184 (± 0.0738)	0.219 (± 0.1547)	0.233 (± 0.1667)	
Lymphocytes, Screening, n=12, 12, 11	2.317 (± 0.5927)	1.953 (± 0.4253)	2.091 (± 0.6873)	
Lymphocytes, Day 1: pre-dose, n=12, 13, 11	2.343 (± 0.6072)	2.001 (± 0.5459)	2.138 (± 0.5642)	
Lymphocytes, Day 1: 4 hr, n=12, 12, 11	2.518 (± 0.7608)	2.204 (± 0.4915)	2.525 (± 0.7586)	
Lymphocytes, Day 4, n=11, 12, 11	2.648 (± 0.7298)	2.114 (± 0.471)	2.466 (± 0.7101)	
Lymphocytes, Day 9, n=12, 13, 12	2.598 (± 0.6504)	2.251 (± 0.5491)	2.513 (± 0.9688)	
Lymphocytes, Day 14, n=12, 12, 12	2.527 (± 0.5543)	2.185 (± 0.6946)	2.554 (± 0.8373)	
Lymphocytes, Day 21, n=12, 13, 12	2.443 (± 0.6599)	2.225 (± 0.5516)	2.559 (± 0.8931)	
Lymphocytes, Day 29: pre-dose, n=12, 13, 12	2.291 (± 0.6079)	1.948 (± 0.5789)	2.204 (± 0.6951)	
Lymphocytes, Day 29: 4 hr, n=12, 13, 11	2.534 (± 0.919)	2.446 (± 0.6275)	2.535 (± 0.8419)	

Lymphocytes, Day 32, n=12, 13, 10	2.428 (± 0.5944)	2.102 (± 0.656)	2.625 (± 0.6761)	
Lymphocytes, Day 42, n=12, 13, 12	2.28 (± 0.5761)	2.063 (± 0.5239)	2.384 (± 0.7138)	
Lymphocytes, Day 57, n=12, 13, 12	2.503 (± 0.5448)	2.211 (± 0.5601)	2.349 (± 0.8857)	
Lymphocytes, Day 85, n=12, 13, 12	2.324 (± 0.4915)	2.126 (± 0.6184)	2.413 (± 0.7779)	
Lymphocytes, Day 120, n=10, 13, 12	2.406 (± 0.3655)	2.122 (± 0.6655)	2.431 (± 0.6785)	
Lymphocytes, Day 165, n=12, 13, 12	2.481 (± 0.608)	2.277 (± 0.6019)	2.639 (± 0.965)	
Lymphocytes, follow-up, n=12, 13, 12	2.487 (± 0.5731)	2.182 (± 0.5712)	2.395 (± 0.9368)	
Monocytes, Screening, n=12, 12, 11	0.468 (± 0.1902)	0.444 (± 0.1418)	0.529 (± 0.1316)	
Monocytes, Day 1: pre-dose, n=12, 13, 11	0.452 (± 0.2115)	0.41 (± 0.1112)	0.591 (± 0.1929)	
Monocytes, Day 1: 4 hr, n=12, 12, 11	0.486 (± 0.2782)	0.464 (± 0.1623)	0.578 (± 0.2161)	
Monocytes, Day 4, n=11, 12, 11	0.564 (± 0.2131)	0.451 (± 0.1527)	0.553 (± 0.156)	
Monocytes, Day 9, n=12, 13, 12	0.551 (± 0.1814)	0.445 (± 0.1359)	0.601 (± 0.1812)	
Monocytes, Day 14, n=12, 12, 12	0.53 (± 0.153)	0.412 (± 0.1216)	0.567 (± 0.1654)	
Monocytes, Day 21, n=12, 13, 12	0.495 (± 0.2371)	0.439 (± 0.1556)	0.579 (± 0.1896)	
Monocytes, Day 29: pre-dose, n=12, 13, 12	0.52 (± 0.2108)	0.412 (± 0.2101)	0.483 (± 0.1345)	
Monocytes, Day 29: 4 hr, n=12, 13, 11	0.46 (± 0.2046)	0.481 (± 0.2329)	0.467 (± 0.1995)	
Monocytes, Day 32, n=12, 13, 10	0.524 (± 0.1996)	0.427 (± 0.161)	0.542 (± 0.1701)	
Monocytes, Day 42, n=12, 13, 12	0.508 (± 0.1889)	0.437 (± 0.1413)	0.526 (± 0.1477)	
Monocytes, Day 57, n=12, 13, 12	0.47 (± 0.1399)	0.414 (± 0.1281)	0.499 (± 0.1303)	
Monocytes, Day 85, n=12, 13, 12	0.503 (± 0.2007)	0.412 (± 0.0966)	0.505 (± 0.142)	
Monocytes, Day 120, n=10, 13, 12	0.503 (± 0.1905)	0.451 (± 0.1327)	0.561 (± 0.1402)	
Monocytes, Day 165, n=12, 13, 12	0.501 (± 0.1996)	0.457 (± 0.1375)	0.581 (± 0.1507)	
Monocytes, follow-up, n=12, 13, 12	0.518 (± 0.1865)	0.437 (± 0.1496)	0.562 (± 0.1711)	
SN, Screening, n=12, 12, 11	5.658 (± 1.3836)	4.668 (± 0.6027)	4.772 (± 0.9135)	
SN, Day 1: pre-dose, n=12, 13, 11	4.954 (± 1.4938)	4.72 (± 0.6397)	5.231 (± 1.0358)	
SN, Day 1: 4 hr, n=12, 12, 11	5.373 (± 1.3816)	4.793 (± 1.0974)	4.85 (± 1.1057)	
SN, Day 4, n=11, 12, 11	5.729 (± 2.5059)	5.228 (± 2.6104)	4.43 (± 1.0647)	
SN, Day 9, n=12, 13, 12	5.368 (± 1.9487)	4.686 (± 0.8311)	5.444 (± 2.7529)	
SN, Day 14, n=12, 12, 12	4.639 (± 1.524)	4.373 (± 0.6839)	4.836 (± 1.4616)	
SN, Day 21, n=12, 13, 12	5.059 (± 1.3648)	4.536 (± 0.813)	4.655 (± 1.9044)	
SN, Day 29: pre-dose, n=12, 13, 12	4.863 (± 1.2799)	4.545 (± 1.3399)	4.265 (± 0.9905)	

SN, Day 29: 4 hr, n=12, 13, 11	4.793 (± 1.692)	4.93 (± 1.7753)	4.43 (± 0.8664)	
SN, Day 32, n=12, 13, 10	4.951 (± 1.2533)	4.165 (± 0.776)	4.642 (± 1.3905)	
SN, Day 42, n=12, 13, 12	4.608 (± 1.148)	4.312 (± 1.4833)	4.745 (± 2.1018)	
SN, Day 57, n=12, 13, 12	4.852 (± 1.6242)	4.294 (± 0.7175)	4.654 (± 1.0599)	
SN, Day 85, n=12, 13, 12	4.706 (± 1.5539)	4.673 (± 1.0079)	4.43 (± 1.1635)	
SN, Day 120, n=10, 13, 12	4.507 (± 1.1009)	4.198 (± 0.9874)	4.753 (± 1.7489)	
SN, Day 165, n=12, 13, 12	5.13 (± 2.0136)	4.512 (± 0.9273)	4.999 (± 2.0022)	
SN, follow-up, n=12, 13, 12	4.866 (± 1.4912)	4.525 (± 0.6462)	4.787 (± 1.592)	
TN, Screening, n=12, 12, 11	5.658 (± 1.3836)	4.668 (± 0.6027)	4.772 (± 0.9135)	
TN, Day 1: pre-dose, n=12, 13, 11	4.954 (± 1.4938)	4.72 (± 0.6397)	5.231 (± 1.0358)	
TN, Day 1: 4 hr, n=12, 12, 11	5.373 (± 1.3816)	4.793 (± 1.0974)	4.85 (± 1.1057)	
TN, Day 4, n=11, 12, 11	5.729 (± 2.5059)	5.228 (± 2.6104)	4.43 (± 1.0647)	
TN, Day 9, n=12, 13, 12	5.368 (± 1.9487)	4.686 (± 0.8311)	5.444 (± 2.7529)	
TN, Day 14, n=12, 12, 12	4.639 (± 1.524)	4.373 (± 0.6839)	4.836 (± 1.4616)	
TN, Day 21, n=12, 13, 12	5.059 (± 1.3648)	4.536 (± 0.813)	4.655 (± 1.9044)	
TN, Day 29: pre-dose, n=12, 13, 12	4.863 (± 1.2799)	4.545 (± 1.3399)	4.265 (± 0.9905)	
TN, Day 29: 4 hr, n=12, 13, 11	4.793 (± 1.692)	4.93 (± 1.7753)	4.43 (± 0.8664)	
TN, Day 32, n=12, 13, 10	4.951 (± 1.2533)	4.165 (± 0.776)	4.642 (± 1.3905)	
TN, Day 42, n=12, 13, 12	4.608 (± 1.148)	4.312 (± 1.4833)	4.745 (± 2.1018)	
TN, Day 57, n=12, 13, 12	4.852 (± 1.6242)	4.294 (± 0.7175)	4.654 (± 1.0599)	
TN, Day 85, n=12, 13, 12	4.706 (± 1.5539)	4.673 (± 1.0079)	4.43 (± 1.1635)	
TN, Day 120, n=10, 13, 12	4.507 (± 1.1009)	4.198 (± 0.9874)	4.753 (± 1.7489)	
TN, Day 165, n=12, 13, 12	5.13 (± 2.0136)	4.512 (± 0.9273)	4.999 (± 2.0022)	
TN, follow-up, n=12, 13, 12	4.866 (± 1.4912)	4.525 (± 0.6462)	4.787 (± 1.592)	
Platelet count, Screening, n=12, 12, 11	227.2 (± 75.31)	242.3 (± 47.09)	195.4 (± 43.98)	
Platelet count, Day 1: pre-dose, n=12, 13, 11	226.6 (± 60.08)	234.2 (± 46.94)	196.5 (± 46.74)	
Platelet count, Day 1: 4 hr, n=11, 12, 11	225.8 (± 56.85)	235 (± 56.47)	205.6 (± 37.71)	
Platelet count, Day 4, n=11, 12, 11	233.6 (± 48.43)	258.7 (± 48.85)	214.8 (± 51.29)	
Platelet count, Day 9, n=12, 13, 12	228 (± 58.56)	249.2 (± 47.53)	209 (± 53.27)	
Platelet count, Day 14, n=12, 13, 12	236.1 (± 59.29)	238.5 (± 46.69)	222.8 (± 61.53)	
Platelet count, Day 21, n=12, 13, 12	238.2 (± 61.79)	244.2 (± 43.88)	199.9 (± 63.66)	

Platelet count, Day 29: pre-dose, n=12, 12, 12	224.6 (± 57.84)	237 (± 62.61)	185.8 (± 50.99)	
Platelet count, Day 29: 4 hr, n=12, 13, 11	221.4 (± 64.4)	237.8 (± 47.91)	180.9 (± 55.12)	
Platelet count, Day 32, n=12, 13, 10	240.6 (± 63.98)	249.2 (± 50.03)	209.4 (± 53.34)	
Platelet count, Day 42, n=12, 13, 12	234 (± 62.46)	251.8 (± 49.72)	201.9 (± 41.39)	
Platelet count, Day 57, n=12, 12, 12	225.7 (± 67.79)	237.1 (± 60.1)	192.3 (± 35.73)	
Platelet count, Day 85, n=12, 12, 11	221.8 (± 56.57)	244.2 (± 60.92)	200.2 (± 44.46)	
Platelet count, Day 120, n=10, 13, 12	235.2 (± 54.93)	241.5 (± 52.38)	203.4 (± 54.48)	
Platelet count, Day 165, n=12, 13, 12	232.5 (± 57.26)	255.6 (± 59.77)	204.3 (± 58)	
Platelet count, follow-up, n=12, 13, 12	244.5 (± 56.29)	249.5 (± 51.44)	212.2 (± 57.93)	
WBC count, Screening, n=12, 12, 11	8.67 (± 1.815)	7.23 (± 0.757)	7.62 (± 1.494)	
WBC count, Day 1: pre-dose, n=12, 13, 11	8 (± 1.982)	7.36 (± 0.991)	8.21 (± 1.662)	
WBC count, Day 1: 4 hr, n=12, 12, 11	8.58 (± 1.863)	7.7 (± 1.149)	8.17 (± 1.532)	
WBC count, Day 4, n=11, 12, 11	9.21 (± 2.841)	7.98 (± 2.817)	7.71 (± 1.624)	
WBC count, Day 9, n=12, 12, 12	8.74 (± 2.499)	7.6 (± 1.211)	8.88 (± 3.038)	
WBC count, Day 14, n=12, 13, 12	7.97 (± 1.835)	7.18 (± 1.257)	8.23 (± 1.855)	
WBC count, Day 21, n=12, 13, 12	8.26 (± 1.856)	7.45 (± 1.2)	8.08 (± 2.369)	
WBC count, Day 29: pre-dose, n=12, 13, 12	7.94 (± 1.681)	7.13 (± 1.66)	7.2 (± 1.591)	
WBC count, Day 29: 4 hr, n=12, 13, 11	8.02 (± 1.794)	8.1 (± 1.626)	7.65 (± 1.457)	
WBC count, Day 32, n=12, 13, 10	8.13 (± 1.766)	6.92 (± 1.114)	8.11 (± 2.221)	
WBC count, Day 42, n=12, 13, 12	7.65 (± 1.645)	7.02 (± 1.81)	7.94 (± 2.696)	
WBC count, Day 57, n=12, 13, 12	8.08 (± 2.065)	7.12 (± 1.094)	7.78 (± 1.796)	
WBC count, Day 85, n=12, 13, 11	7.79 (± 1.891)	7.38 (± 1.409)	7.62 (± 1.823)	
WBC count, Day 120, n=10, 13, 12	7.69 (± 1.339)	7 (± 1.348)	8.06 (± 2.21)	
WBC count, Day 165, n=12, 13, 12	8.34 (± 2.567)	7.47 (± 1.386)	8.48 (± 2.975)	
WBC count, follow-up, n=12, 13, 12	8.08 (± 1.875)	7.39 (± 1.054)	8.01 (± 2.012)	

Notes:

[28] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[29] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[30] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Hemoglobin and mean corpuscle hemoglobin concentration (MCHC) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Hemoglobin and mean corpuscle hemoglobin concentration (MCHC) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Hemoglobin and MCHC values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[31]	13[32]	12[33]	
Units: Grams per liter (G/L)				
arithmetic mean (standard deviation)				
Hemoglobin, Screening, n=12, 12, 11	156.8 (± 17.52)	149.6 (± 18.31)	149.1 (± 9.98)	
Hemoglobin, Day 1: pre-dose, n=12, 13, 11	150.8 (± 14.28)	145.3 (± 17.72)	144.7 (± 9.1)	
Hemoglobin, Day 1: 4 hr, n=12, 12, 11	145.3 (± 12.11)	139.1 (± 12.65)	137.5 (± 7.57)	
Hemoglobin, Day 4, n=11, 12, 11	152.8 (± 16.33)	142.8 (± 16.26)	143 (± 8.41)	
Hemoglobin, Day 9, n=12, 13, 12	152.7 (± 14.12)	143.2 (± 17.2)	141.4 (± 10.18)	
Hemoglobin, Day 14, n=12, 13, 12	152.8 (± 13.74)	143.2 (± 16.47)	142.1 (± 9.34)	
Hemoglobin, Day 21, n=12, 13, 12	152 (± 13.75)	144.3 (± 16.99)	142.4 (± 11.07)	
Hemoglobin, Day 29: pre-dose, n=12, 13, 12	148.4 (± 13.63)	139.8 (± 17.51)	139.8 (± 11.69)	
Hemoglobin, Day 29: 4 hr, n=12, 13, 11	145.3 (± 14.12)	139.7 (± 17.14)	135.6 (± 8.63)	
Hemoglobin, Day 32, n=12, 13, 10	148.5 (± 12.52)	140.9 (± 17.26)	141.5 (± 11.34)	
Hemoglobin, Day 42, n=12, 13, 12	149.4 (± 12.65)	140.9 (± 17.07)	140.4 (± 11.08)	
Hemoglobin, Day 57, n=12, 13, 12	149.9 (± 13.7)	140.2 (± 17.51)	141 (± 11.95)	
Hemoglobin, Day 85, n=12, 13, 12	150.5 (± 16.28)	142.5 (± 16.57)	139 (± 11.1)	
Hemoglobin, Day 120, n=10, 13, 12	151.4 (± 17.37)	142.3 (± 20.33)	141.9 (± 13.96)	
Hemoglobin, Day 165, n=12, 13, 12	150.6 (± 15.62)	142.5 (± 20.28)	140.3 (± 13.72)	
Hemoglobin, follow-up, n=12, 13, 12	151.3 (± 14.69)	142.1 (± 22.08)	139.8 (± 12.63)	
MCHC, Screening, n=12, 12, 11	326.6 (± 9.06)	324.4 (± 7.86)	327.4 (± 11.29)	
MCHC, Day 1: pre-dose, n=12, 13, 11	326.6 (± 7.69)	322.8 (± 10.43)	327.6 (± 10.06)	
MCHC, Day 1: 4 hr, n=12, 12, 11	325 (± 6.52)	320.8 (± 11.26)	326.5 (± 7.83)	
MCHC, Day 4, n=11, 12, 11	326.4 (± 10.54)	325.8 (± 8.08)	327.4 (± 6.44)	
MCHC, Day 9, n=12, 13, 12	328.5 (± 11.21)	323.3 (± 6.51)	327.7 (± 11.48)	
MCHC, Day 14, n=12, 13, 12	325.2 (± 8.39)	325.1 (± 9.73)	328.8 (± 7.69)	
MCHC, Day 21, n=12, 13, 12	325.3 (± 8.76)	324.3 (± 6.34)	326.5 (± 6.74)	
MCHC, Day 29: pre-dose, n=12, 13, 12	326 (± 11.1)	320.1 (± 11.75)	320.8 (± 13.04)	

MCHC, Day 29: 4 hr, n=12, 13, 11	323 (± 7.16)	318.6 (± 10.34)	323.1 (± 11.67)	
MCHC, Day 32, n=12, 13, 10	326.9 (± 11.47)	323.2 (± 8.98)	325.1 (± 6.3)	
MCHC, Day 42, n=12, 13, 12	324.8 (± 9.61)	321.5 (± 10.96)	322.6 (± 9.1)	
MCHC, Day 57, n=12, 13, 12	323.8 (± 11.34)	321.2 (± 9.55)	323.2 (± 6.45)	
MCHC, Day 85, n=12, 13, 12	323.2 (± 10.22)	317.8 (± 8.27)	320.2 (± 7.4)	
MCHC, Day 120, n=10, 13, 12	321.3 (± 7.59)	319 (± 9.49)	319.8 (± 7.85)	
MCHC, Day 165, n=12, 13, 12	322.4 (± 9.77)	318.9 (± 7.24)	319 (± 6.81)	
MCHC, follow-up, n=12, 13, 12	319.3 (± 11.52)	318.8 (± 8.86)	319 (± 9.12)	

Notes:

[31] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[32] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[33] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Hematocrit values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Hematocrit values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Hematocrit values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[34]	13[35]	12[36]	
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Screening, n=12, 12, 11	0.4799 (± 0.05006)	0.461 (± 0.05737)	0.4555 (± 0.03407)	
Day 1: pre-dose, n=12, 13, 11	0.4607 (± 0.03855)	0.4504 (± 0.05399)	0.4419 (± 0.03158)	
Day 1: 4 hr, n=12, 12, 11	0.4468 (± 0.03652)	0.4341 (± 0.04154)	0.4214 (± 0.02543)	
Day 4, n=11, 12, 11	0.4682 (± 0.05106)	0.4387 (± 0.05038)	0.4371 (± 0.02468)	
Day 9, n=12, 13, 12	0.4649 (± 0.04146)	0.4432 (± 0.05507)	0.4315 (± 0.03044)	

Day 14, n=12, 13, 12	0.4701 (± 0.03889)	0.4408 (± 0.05164)	0.4321 (± 0.02489)	
Day 21, n=12, 13, 12	0.4673 (± 0.04176)	0.4454 (± 0.05511)	0.4364 (± 0.03362)	
Day 29: pre-dose, n=12, 13, 12	0.4551 (± 0.03785)	0.4368 (± 0.04971)	0.4361 (± 0.03512)	
Day 29: 4 hr, n=12, 13, 11	0.45 (± 0.04137)	0.4385 (± 0.05347)	0.4197 (± 0.02605)	
Day 32, n=12, 13, 10	0.4547 (± 0.03776)	0.4361 (± 0.05536)	0.4354 (± 0.03389)	
Day 42, n=12, 13, 12	0.4609 (± 0.04166)	0.4387 (± 0.0532)	0.4353 (± 0.03217)	
Day 57, n=12, 13, 12	0.4628 (± 0.03985)	0.4368 (± 0.05354)	0.4366 (± 0.03679)	
Day 85, n=12, 13, 12	0.4653 (± 0.04823)	0.4483 (± 0.05264)	0.4345 (± 0.0368)	
Day 120, n=10, 13, 12	0.4717 (± 0.05091)	0.4457 (± 0.06294)	0.4442 (± 0.04487)	
Day 165, n=12, 13, 12	0.4676 (± 0.04512)	0.4458 (± 0.05822)	0.4394 (± 0.04186)	
Follow-up, n=12, 13, 12	0.4733 (± 0.03656)	0.4454 (± 0.06752)	0.4381 (± 0.03863)	

Notes:

[34] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[35] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[36] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Mean corpuscle hemoglobin (MCH) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Mean corpuscle hemoglobin (MCH) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

MCH values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[37]	13[38]	12[39]	
Units: Picograms				
arithmetic mean (standard deviation)				
Screening, n=12, 12, 11	30.46 (± 1.743)	29.58 (± 1.736)	31.35 (± 2.23)	
Day 1: pre-dose, n=12, 13, 11	30.67 (± 1.793)	29.76 (± 1.531)	31.1 (± 2.385)	

Day 1: 4 hr, n=12, 12, 11	30.78 (± 1.88)	29.53 (± 1.555)	30.64 (± 1.967)	
Day 4, n=11, 12, 11	30.74 (± 1.989)	29.68 (± 1.73)	31.02 (± 2.101)	
Day 9, n=12, 13, 12	30.8 (± 1.805)	29.57 (± 1.625)	31.05 (± 2.345)	
Day 14, n=12, 13, 12	30.52 (± 1.7)	29.83 (± 1.666)	31.03 (± 2.214)	
Day 21, n=12, 13, 12	30.58 (± 1.693)	29.68 (± 1.496)	30.89 (± 2.381)	
Day 29: pre-dose, n=12, 13, 12	30.74 (± 1.931)	29.5 (± 1.694)	30.58 (± 2.482)	
Day 29: 4 hr, n=12, 13, 11	30.62 (± 1.712)	29.58 (± 1.585)	31.05 (± 2.649)	
Day 32, n=12, 13, 10	30.69 (± 1.834)	29.6 (± 1.759)	30.59 (± 2.227)	
Day 42, n=12, 13, 12	30.48 (± 1.698)	29.42 (± 1.672)	30.68 (± 2.51)	
Day 57, n=12, 13, 12	30.37 (± 1.861)	29.42 (± 1.912)	30.63 (± 2.623)	
Day 85, n=12, 13, 12	30.15 (± 1.822)	28.98 (± 1.983)	30.33 (± 2.5)	
Day 120, n=10, 13, 12	29.72 (± 2.059)	28.93 (± 2.197)	29.94 (± 2.405)	
Day 165, n=12, 13, 12	29.67 (± 2.195)	28.62 (± 2.378)	29.27 (± 2.597)	
Follow-up, n=12, 13 12	29.49 (± 2.198)	28.62 (± 2.3)	29.51 (± 2.652)	

Notes:

[37] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[38] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[39] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Mean corpuscle volume (MCV) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Mean corpuscle volume (MCV) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

MCV values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[40]	13[41]	12[42]	
Units: Femtoliters				
arithmetic mean (standard deviation)				
Screening, n=12, 12, 11	93.3 (± 4.74)	91.3 (± 4.25)	95.7 (± 5.22)	
Day 1: pre-dose, n=12, 13, 11	94 (± 4.67)	92.3 (± 4.48)	95 (± 5.8)	
Day 1: 4 hr, n=12, 12, 11	94.7 (± 4.83)	92 (± 4.11)	94 (± 4.2)	
Day 4, n=11, 12, 11	94 (± 4.6)	91.3 (± 4.59)	94.7 (± 6.21)	
Day 9, n=12, 13, 12	93.6 (± 4.74)	91.4 (± 3.91)	94.8 (± 5.72)	
Day 14, n=12, 13, 12	94 (± 4.39)	91.8 (± 4.52)	94.4 (± 6.87)	
Day 21, n=12, 13, 12	94.2 (± 3.97)	91.6 (± 4.65)	94.7 (± 6.5)	
Day 29: pre-dose, n=12, 13, 12	94.3 (± 4.44)	92.2 (± 5.32)	95.4 (± 6.89)	
Day 29: 4 hr, n=12, 13, 11	94.8 (± 4.81)	93 (± 5.12)	96.1 (± 6.88)	
Day 32, n=12, 13, 10	93.9 (± 4.25)	91.6 (± 4.21)	94.1 (± 7.13)	
Day 42, n=12, 13, 12	93.8 (± 3.93)	91.5 (± 4.99)	95.2 (± 7.23)	
Day 57, n=12, 13, 12	93.8 (± 4.11)	91.6 (± 4.84)	94.9 (± 7.46)	
Day 85, n=12, 13, 12	93.3 (± 3.87)	91.2 (± 5.12)	94.8 (± 6.98)	
Day 120, n=10, 13, 12	92.6 (± 5.04)	90.8 (± 5.82)	93.7 (± 6.17)	
Day 165, n=12, 13, 12	92 (± 5.67)	89.8 (± 5.85)	91.8 (± 6.63)	
Follow-up, n=12, 13, 12	92.3 (± 5.61)	89.8 (± 5.6)	92.3 (± 6.77)	

Notes:

[40] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[41] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[42] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Red blood cell (RBC) count values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Red blood cell (RBC) count values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

RBC count values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[43]	13[44]	12[45]	
Units: 10^12 cells per liter (TI/L)				
arithmetic mean (standard deviation)				
Screening, n=12, 12, 11	5.16 (± 0.568)	5.06 (± 0.661)	4.77 (± 0.473)	
Day 1: pre-dose, n=12, 13, 11	4.92 (± 0.449)	4.89 (± 0.595)	4.68 (± 0.5)	
Day 1: 4 hr, n=12, 12, 11	4.72 (± 0.404)	4.73 (± 0.449)	4.5 (± 0.412)	
Day 4, n=11, 12, 11	4.97 (± 0.471)	4.83 (± 0.583)	4.64 (± 0.437)	
Day 9, n=12, 13, 12	4.98 (± 0.411)	4.85 (± 0.613)	4.59 (± 0.523)	
Day 14, n=12, 13, 12	5.01 (± 0.365)	4.8 (± 0.564)	4.61 (± 0.542)	
Day 21, n=12, 13, 12	4.97 (± 0.384)	4.88 (± 0.596)	4.66 (± 0.611)	
Day 29: pre-dose, n=12, 13, 12	4.85 (± 0.368)	4.74 (± 0.55)	4.61 (± 0.598)	
Day 29: 4 hr, n=12, 13, 11	4.76 (± 0.378)	4.73 (± 0.545)	4.4 (± 0.506)	
Day 32, n=10, 13, 10	4.85 (± 0.361)	4.76 (± 0.605)	4.66 (± 0.572)	
Day 42, n=12, 13, 12	4.92 (± 0.404)	4.8 (± 0.557)	4.63 (± 0.645)	
Day 57, n=12, 13, 12	4.96 (± 0.408)	4.78 (± 0.564)	4.65 (± 0.664)	
Day 85, n=12, 13, 12	4.98 (± 0.427)	4.92 (± 0.537)	4.62 (± 0.608)	
Day 120, n=10, 13, 12	5.1 (± 0.478)	4.93 (± 0.612)	4.77 (± 0.679)	
Day 165, n=12, 13, 12	5.09 (± 0.36)	4.98 (± 0.554)	4.82 (± 0.671)	
Follow-up, n=12, 13, 12	5.15 (± 0.34)	4.97 (± 0.687)	4.79 (± 0.637)	

Notes:

[43] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[44] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[45] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Systolic blood pressure (SBP) and diastolic blood pressure (DBP) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Systolic blood pressure (SBP) and diastolic blood pressure (DBP) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

SBP and DBP values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[46]	13[47]	12[48]	
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
SBP, Screening	141.9 (± 14.12)	139.7 (± 15.11)	145.5 (± 14.37)	
SBP, Day 1: pre-dose	141.5 (± 6.78)	139.2 (± 11.68)	140.9 (± 16.41)	
SBP, Day 1: 4 hr	139.7 (± 16.09)	139.8 (± 8.8)	138 (± 16.14)	
SBP, Day 4	140 (± 12.99)	137.5 (± 18.45)	141.5 (± 10.94)	
SBP, Day 9	136.3 (± 14.33)	137.3 (± 20.86)	140.4 (± 18.66)	
SBP, Day 14	139.2 (± 12.43)	136.9 (± 15.12)	135.9 (± 21)	
SBP, Day 21	133.1 (± 16.03)	142.3 (± 14.99)	139.9 (± 11.67)	
SBP, Day 29: pre-dose	133.9 (± 13.94)	139 (± 17)	140.7 (± 9.73)	
SBP, Day 29: 4 hr	132.6 (± 11.98)	141.2 (± 17.39)	146.5 (± 12.7)	
SBP, Day 32	137.4 (± 14.11)	136.1 (± 13.02)	143.5 (± 13.86)	
SBP, Day 42	134.8 (± 15.46)	137.4 (± 16.48)	135.3 (± 18.4)	
SBP, Day 57	136.7 (± 12.99)	134.8 (± 15.59)	133.3 (± 12.15)	
SBP, Day 85	133.8 (± 14.54)	138.3 (± 11.56)	140 (± 11.69)	
SBP, Day 120	132.1 (± 15.68)	134.2 (± 13.47)	147.2 (± 11.27)	
SBP, Day 165	131.7 (± 17.33)	136.2 (± 13.53)	137.9 (± 17.05)	
SBP, follow-up	131.9 (± 14.2)	139.3 (± 14.44)	137.3 (± 13.36)	
DBP, Screening	85.3 (± 5.37)	84.5 (± 8.38)	85.4 (± 7.45)	
DBP, Day 1: pre-dose	84.3 (± 8.85)	81.8 (± 6.31)	80.4 (± 8.73)	
DBP, Day 1: 4 hr	80.8 (± 7.09)	80.5 (± 5.01)	77.7 (± 11.08)	
DBP, Day 4	82.6 (± 8.01)	77.6 (± 9.42)	82.7 (± 6.83)	
DBP, Day 9	80.5 (± 7.27)	80.5 (± 8.81)	81.8 (± 7.44)	
DBP, Day 14	84.3 (± 7.33)	79.9 (± 6.75)	76.5 (± 14.81)	
DBP, Day 21	80.8 (± 6.04)	81.4 (± 6.13)	77.2 (± 9.28)	
DBP, Day 29: pre-dose	80.1 (± 9.55)	83.1 (± 11)	81.8 (± 8.44)	
DBP, Day 29: 4 hr	77.4 (± 7.66)	80.3 (± 7.38)	79.2 (± 8.55)	
DBP, Day 32	80.8 (± 8.62)	80.2 (± 6.26)	80 (± 12.67)	
DBP, Day 42	79.3 (± 4.85)	79.2 (± 8.02)	77.3 (± 10.25)	
DBP, Day 57	81.3 (± 8.09)	77.5 (± 7.08)	79.2 (± 9.72)	
DBP, Day 85	77.8 (± 8.09)	81.6 (± 8.44)	76 (± 7.45)	
DBP, Day 120	81.5 (± 7.15)	78.9 (± 5.17)	85.6 (± 7.28)	
DBP, Day 165	79.1 (± 9.73)	79.8 (± 9.33)	80.3 (± 9.38)	
DBP, follow-up	81.2 (± 9.25)	81 (± 7.31)	80.1 (± 8.66)	

Notes:

[46] - All Subject Population

[47] - All Subject Population

[48] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Heart rate (HR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Heart rate (HR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

HR values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[49]	13[50]	12[51]	
Units: Beats per minute				
arithmetic mean (standard deviation)				
Screening	71.5 (± 9.49)	77.8 (± 12.62)	74.8 (± 9.18)	
Day 1: pre-dose	72.8 (± 6.73)	79.9 (± 10.7)	72.3 (± 7.63)	
Day 1: 4 hr	74.1 (± 11.37)	79.2 (± 10.64)	74.2 (± 10.03)	
Day 4	73.6 (± 8.27)	78.9 (± 15.53)	72.9 (± 8.26)	
Day 9	69.7 (± 9.26)	76.3 (± 11.24)	74.8 (± 14.45)	
Day 14	71.2 (± 11.64)	77.4 (± 9.63)	74.8 (± 9.2)	
Day 21	69 (± 9.17)	77.6 (± 9.25)	72.7 (± 11.04)	
Day 29: pre-dose	70.3 (± 9.19)	78.3 (± 11.13)	69.5 (± 7)	
Day 29: 4 hr	72.4 (± 10.23)	82.2 (± 12.05)	72.1 (± 10.44)	
Day 32	69.6 (± 10.19)	78 (± 10.52)	71.7 (± 11.06)	
Day 42	69.4 (± 11.29)	75.2 (± 11.63)	72.8 (± 14.48)	
Day 57	70.5 (± 9.44)	76.3 (± 11.66)	71.3 (± 10.03)	
Day 85	70.1 (± 8.86)	78.5 (± 10.32)	70.3 (± 4.83)	
Day 120	67.3 (± 9.72)	76.5 (± 10.07)	74 (± 13.1)	
Day 165	70.1 (± 10.32)	77.1 (± 11.21)	73.8 (± 9.37)	
Follow-up	69.2 (± 10.85)	75.5 (± 12.37)	71.4 (± 10.5)	

Notes:

[49] - All Subject Population

[50] - All Subject Population

[51] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Respiration rate (RR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Respiration rate (RR) values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

RR values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[52]	13[53]	12[54]	
Units: breaths per minute				
arithmetic mean (standard deviation)				
Screening	16 (± 2.52)	16.3 (± 3.22)	17.2 (± 2.41)	
Day 1: pre-dose	16 (± 2.34)	15.8 (± 2.51)	17.2 (± 2.44)	
Day 1: 4 hr	17.8 (± 3.05)	15.9 (± 3.9)	18.2 (± 3.83)	
Day 4	15.5 (± 1.83)	15.5 (± 2.63)	17.3 (± 2.96)	
Day 9	16.6 (± 2.91)	15.6 (± 2.53)	16.7 (± 2.15)	
Day 14	16.3 (± 2.42)	15.1 (± 3.09)	16.7 (± 2.1)	
Day 21	15.6 (± 2.8)	15.2 (± 2.73)	16.9 (± 2.39)	
Day 29: pre-dose	16.7 (± 2.71)	15.4 (± 2.53)	17.7 (± 3.31)	
Day 29: 4 hr	16.9 (± 3.63)	15.9 (± 4.25)	18.7 (± 3.68)	
Day 32	15.9 (± 2.5)	14.8 (± 3.08)	16.8 (± 2.45)	
Day 42	15.6 (± 2.75)	15 (± 2.94)	17.8 (± 3.07)	
Day 57	15.8 (± 2.08)	15.3 (± 2.75)	17.2 (± 2.41)	
Day 85	16.2 (± 1.9)	15 (± 2.08)	17 (± 2.09)	
Day 120	16.3 (± 1.71)	15.5 (± 2.47)	16.5 (± 2.43)	
Day 165	16.3 (± 1.87)	15.4 (± 2.06)	16.2 (± 2.21)	
Follow-up	16.1 (± 1.98)	14.6 (± 2.18)	16.3 (± 1.54)	

Notes:

[52] - All Subject Population

[53] - All Subject Population

[54] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Body temperature values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Body temperature values at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Body temperature values were assessed at Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up.

End point type	Secondary

End point timeframe:

Screening; Days 1 (pre-dose and 4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[55]	13[56]	12[57]	
Units: Degrees centigrade				
arithmetic mean (standard deviation)				
Screening	35.98 (± 0.449)	36.22 (± 0.436)	35.87 (± 0.764)	
Day 1: pre-dose	35.85 (± 0.403)	35.93 (± 0.501)	35.9 (± 0.558)	
Day 1: 4 hr	36.33 (± 0.374)	36.06 (± 0.415)	36.07 (± 0.733)	
Day 4	35.91 (± 0.287)	36.07 (± 0.494)	35.98 (± 0.583)	
Day 9	35.74 (± 0.511)	36.06 (± 0.715)	35.96 (± 0.673)	
Day 14	35.83 (± 0.566)	35.82 (± 0.483)	35.93 (± 0.409)	
Day 21	35.94 (± 0.329)	35.83 (± 0.545)	35.98 (± 0.447)	
Day 29: pre-dose	35.89 (± 0.378)	35.81 (± 0.386)	36 (± 0.531)	
Day 29: 4 hr	36.13 (± 0.611)	36.09 (± 0.448)	35.92 (± 0.517)	
Day 32	35.71 (± 0.32)	35.88 (± 0.554)	35.78 (± 0.546)	
Day 42	35.82 (± 0.379)	35.91 (± 0.206)	36.01 (± 0.507)	
Day 57	35.81 (± 0.454)	35.97 (± 0.473)	35.83 (± 0.697)	

Day 85	35.77 (± 0.274)	35.65 (± 0.448)	35.84 (± 0.56)	
Day 120	35.93 (± 0.293)	35.97 (± 0.312)	35.58 (± 0.636)	
Day 165	35.78 (± 0.331)	36.01 (± 0.441)	35.6 (± 0.673)	
Follow-up	35.8 (± 0.313)	36.03 (± 0.357)	35.74 (± 0.611)	

Notes:

[55] - All Subject Population

[56] - All Subject Population

[57] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Electrocardiogram (ECG) measurements at Screening, Day 1 (pre-dose and 1 hr and 4 hr post-dose), and Day 29 (pre-dose and 1 hr and 4 hr post-dose)

End point title	Electrocardiogram (ECG) measurements at Screening, Day 1 (pre-dose and 1 hr and 4 hr post-dose), and Day 29 (pre-dose and 1 hr and 4 hr post-dose)

End point description:

ECG measurements included PR interval, QRS duration, QT interval, corrected QT (QTc) interval, corrected QT by Bazett's formula (QTcB) interval, corrected QT by Fridericia's formula (QTcF) interval, and RR interval.

End point type	Secondary

End point timeframe:

Screening, Day 1 (pre-dose; 1 and 4 hr post-dose), and Day 29 (pre-dose; 1 hr and 4 hr post-dose)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[58]	13[59]	12[60]	
Units: milliseconds				
arithmetic mean (standard deviation)				
PR Interval, Screening, n=12, 13, 11	160.1 (± 32.8)	162.7 (± 19.55)	163.7 (± 19.84)	
PR Interval, Day 1: pre-dose, n=12, 13, 11	167.9 (± 25.29)	170.4 (± 16.16)	160.5 (± 19.23)	
PR Interval, Day 1: 1 hr, n=12, 13, 11	166.2 (± 27.83)	169.5 (± 18.96)	162.6 (± 17.38)	
PR Interval, Day 1: 4 hr, n=12, 13, 11	167 (± 32.19)	164.9 (± 18.2)	164.5 (± 22.11)	
PR Interval, Day 29, pre-dose, n=12, 13, 11	167.1 (± 35.51)	163.4 (± 15.22)	159.8 (± 30.41)	
PR Interval, Day 29: 1 hr, n=12, 13, 11	156.8 (± 35.19)	171.8 (± 15.58)	159.3 (± 31.05)	
PR Interval, Day 29: 4 hr, n=12, 13, 11	162.2 (± 37.64)	167.7 (± 20.36)	159.4 (± 32.06)	
QRS duration, Screening, n=12, 13, 12	105.8 (± 28.17)	94.2 (± 24.15)	102.9 (± 18.66)	
QRS duration, Day 1: pre-dose, n=12, 13, 12	101.6 (± 27.56)	93.5 (± 23.99)	103.6 (± 15.04)	

QRS duration, Day 1: 1 hr, n=12, 13, 12	105.5 (± 29.18)	94.2 (± 23.5)	98.9 (± 15.83)	
QRS duration, Day 1: 4 hr, n=12, 13, 12	104.4 (± 28.81)	92.3 (± 26.7)	103.9 (± 15.13)	
QRS duration, Day 29, pre-dose, n=12, 12, 12	103.2 (± 28.9)	92.8 (± 24.08)	101.8 (± 12.76)	
QRS duration, Day 29: 1 hr, n=12, 13, 12	103.1 (± 27.87)	96.4 (± 22.34)	101.3 (± 19.14)	
QRS duration, Day 29: 4 hr, n=12, 13, 12	104.5 (± 26.06)	95.8 (± 23.96)	102.5 (± 16.19)	
QT interval, Screening, n=12, 13, 12	377.6 (± 41.54)	365.2 (± 32.26)	385.6 (± 28.38)	
QT interval, Day 1: pre-dose, n=12, 13, 12	390.8 (± 31.12)	356.7 (± 28.42)	380.8 (± 24.44)	
QT interval, Day 1: 1 hr, n=12, 13, 12	389.1 (± 33.1)	362.8 (± 34.09)	386 (± 27.82)	
QT interval, Day 1: 4 hr, n=12, 13, 12	374.6 (± 43.03)	345.5 (± 30.49)	374.6 (± 28.88)	
QT interval, Day 29, pre-dose, n=12, 12, 12	379.9 (± 35.08)	353.8 (± 20.36)	382.2 (± 23.59)	
QT interval, Day 29: 1 hr, n=12, 13, 12	393.4 (± 36.63)	368.1 (± 32.66)	386.1 (± 33.29)	
QT interval, Day 29: 4 hr, n=12, 13, 12	378.8 (± 33.13)	356.2 (± 29.24)	375.4 (± 30.34)	
QTc interval, Screening, n=5, 8, 5	396.6 (± 43.69)	401.1 (± 24.31)	402.4 (± 24.69)	
QTc interval, Day 1: pre-dose, n=5, 9, 5	415 (± 22.46)	401 (± 26.37)	399.6 (± 25.99)	
QTc interval, Day 1: 1 hr, n=5, 9, 5	409 (± 31.71)	402.7 (± 32.39)	373 (± 21.83)	
QTc interval, Day 1: 4 hr, n=5, 9, 6	414.6 (± 23.33)	392.3 (± 25.5)	391.8 (± 23.03)	
QTc interval, Day 29, pre-dose, n=5, 8, 5	408.5 (± 26.41)	395 (± 27.81)	394.8 (± 26.11)	
QTc interval, Day 29: 1 hr, n=5, 8, 4	405 (± 29.26)	406.4 (± 29.18)	391 (± 21.69)	
QTc interval, Day 29: 4 hr, n=5, 8, 5	415.4 (± 20.47)	401.3 (± 27.59)	396.8 (± 26.53)	
QTcB interval, Screening, n=7, 5, 7	428.9 (± 66.45)	438.2 (± 73.43)	458.7 (± 82.52)	
QTcB interval, Day 1: pre-dose, n=7, 4, 7	446.4 (± 87.83)	444.5 (± 83)	450.6 (± 82.8)	
QTcB interval, Day 1: 1 hr	425.6 (± 69.63)	435.8 (± 89.82)	440 (± 89.05)	
QTcB interval, Day 1: 4 hr, n=7, 4, 7	422.1 (± 69.64)	441.5 (± 87.44)	451.5 (± 90.65)	
QTcB interval, Day 29, pre-dose, n=7, 4, 6	429.4 (± 70.44)	441.5 (± 87.64)	435.9 (± 87.94)	
QTcB interval, Day 29: 1 hr, n=7, 5, 8	428.4 (± 94.13)	425 (± 81.65)	440.6 (± 79.75)	
QTcB interval, Day 29: 4 hr, n=7, 5, 7	422 (± 69.14)	427.2 (± 80.83)	441 (± 87.06)	
QTcF interval, Screening, n=7, 5, 7	413.7 (± 44.18)	416 (± 41.6)	434.6 (± 54.29)	
QTcF interval, Day 1: pre-dose, n=7, 4, 7	427.9 (± 60.53)	416.8 (± 48.73)	427.9 (± 54.86)	
QTcF interval, Day 1: 1 hr, n=7, 4, 7	412.3 (± 45.59)	415.3 (± 49.45)	423.3 (± 59.13)	
QTcF interval, Day 1: 4 hr, n=7, 4, 6	408 (± 47.9)	415 (± 49.99)	425 (± 61.7)	
QTcF interval, Day 29, pre-dose, n=7, 4, 7	412.4 (± 47.74)	411.8 (± 54.02)	415.7 (± 58.11)	

QTcF interval, Day 29: 1 hr, n=7, 5, 8	417.7 (± 63.81)	408.4 (± 45.69)	421.4 (± 53.3)	
QTcF interval, Day 29: 4 hr, n=7, 5, 7	408.7 (± 44.66)	406.6 (± 46.65)	416.6 (± 59.57)	
RR interval, Screening, n=7, 5, 7	865.7 (± 243.54)	806.2 (± 285.39)	778.7 (± 208.89)	
RR interval, Day 1: pre-dose, n=7, 4, 7	834.9 (± 210.7)	746.8 (± 250.85)	783.3 (± 197.1)	
RR interval, Day 1: 1 hr, n=7, 4, 7	883.3 (± 230.65)	851.8 (± 347.73)	865 (± 235.3)	
RR interval, Day 1: 4 hr, n=7, 4, 6	873.7 (± 239.34)	771.5 (± 304.19)	747 (± 188.66)	
RR interval, Day 29, pre-dose, n=7, 4, 7	842.6 (± 217.13)	718 (± 219.91)	813.7 (± 210.22)	
RR interval, Day 29: 1 hr, n=7, 5, 8	942.9 (± 257.89)	893 (± 366.89)	823.3 (± 223.16)	
RR interval, Day 29: 4 hr, n=7, 5, 7	888.1 (± 237.25)	825.6 (± 296.3)	764.4 (± 204.75)	

Notes:

[58] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[59] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[60] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in glycohemoglobin A1c (% HbA1c) at Days 29, 57, and 85

End point title	Change from Baseline in glycohemoglobin A1c (% HbA1c) at Days 29, 57, and 85

End point description:

HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a period of time. The Baseline HbA1c value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[61]	13[62]	12[63]	
Units: Percentage of HbA1c in the blood				
arithmetic mean (standard deviation)				
Day 29, n=12, 12, 12	-0.34 (± 0.281)	-0.2 (± 0.266)	-0.42 (± 0.469)	
Day 57, n=11, 13, 12	-0.6 (± 0.642)	-0.37 (± 0.411)	-0.61 (± 0.768)	
Day 85, n=12, 12, 11	-0.51 (± 0.847)	-0.3 (± 0.541)	-0.86 (± 0.717)	

Notes:

[61] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[62] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).
[63] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in fasting blood insulin from the post-mixed meal test (MMT) at pre-meal and 15, 30, 60, 90, 120, 180, and 250 minutes post-meal at Days 29, 57, and 85

End point title	Change from Baseline in fasting blood insulin from the post-mixed meal test (MMT) at pre-meal and 15, 30, 60, 90, 120, 180, and 250 minutes post-meal at Days 29, 57, and 85

End point description:

The Baseline fasting blood insulin value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary

End point timeframe:

Baseline; pre-meal; and 15, 30, 60, 90, 120, 180, and 250 post-meal at Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[64]	13[65]	12[66]	
Units: Picomoles per liter				
arithmetic mean (standard deviation)				
Day 29: pre-meal, n=12, 13, 11	-4 (± 35.017)	26.31 (± 86.065)	21.27 (± 51.5)	
Day 29: 15 minutes (min), n=12, 13, 11	62.5 (± 104.377)	119.08 (± 123.665)	176.73 (± 220.933)	
Day 29: 30 min, n=12, 13, 11	120.5 (± 145.435)	222.46 (± 286.302)	181.09 (± 166.186)	
Day 29: 60 min, n=11, 13, 11	204.55 (± 121.089)	246 (± 279.971)	272.18 (± 207.174)	
Day 29: 90 min, n=11, 13, 11	153.27 (± 74.62)	192.92 (± 267.733)	160.36 (± 131.839)	
Day 29: 120 min, n=11, 13, 11	97.64 (± 82.447)	131.08 (± 182.382)	91.09 (± 110.921)	
Day 29: 180 min, n=12, 13, 11	55 (± 58.387)	36 (± 88.657)	8.18 (± 68.897)	
Day 29: 240 min, n=12, 13, 11	22 (± 46.92)	5.54 (± 63.708)	-21.27 (± 69.11)	
Day 57: pre-meal, n=12, 13, 11	2.5 (± 21.928)	12.46 (± 46.699)	-15.82 (± 57.941)	
Day 57: 15 min, n=12, 13, 11	44 (± 88.896)	176.77 (± 334.035)	105.27 (± 94.654)	
Day 57: 30 min, n=12, 13, 11	156.5 (± 136.329)	266.31 (± 456.641)	147.27 (± 141.131)	
Day 57: 60 min, n=12, 13, 11	211.5 (± 115.586)	243.69 (± 163.044)	247.64 (± 212.439)	

Day 57: 90 min, n=11, 13, 11	168 (± 49.332)	214.62 (± 128.058)	205.09 (± 187.116)	
Day 57: 120 min, n=12, 13, 11	125.5 (± 73.282)	109.38 (± 104.216)	131.45 (± 126.156)	
Day 57: 180 min, n=12, 13, 11	27 (± 58.481)	21.69 (± 39.462)	23.45 (± 50.447)	
Day 57: 240 min, n=12, 13, 10	2.5 (± 33.008)	-18.92 (± 70.605)	-5.4 (± 55.169)	
Day 85: pre-meal, n=12, 13, 10	1 (± 33.439)	17.08 (± 60.441)	10.2 (± 70.316)	
Day 85: 15 min, n=12, 13, 11	29 (± 39.372)	94.15 (± 129.901)	140.73 (± 224.906)	
Day 85: 30 min, n=12, 13, 11	194 (± 240.223)	194.77 (± 174.389)	176.18 (± 221.046)	
Day 85: 60 min, n=12, 13, 11	174.5 (± 102.479)	271.85 (± 334.096)	250.36 (± 180.122)	
Day 85: 90 min, n=12, 13, 11	151.5 (± 69.036)	218.31 (± 153.803)	197.45 (± 131.356)	
Day 85: 120 min, n=12, 13, 11	140 (± 73.187)	175.85 (± 206.461)	129.27 (± 148.076)	
Day 85: 180 min, n=12, 13, 11	32 (± 60.831)	28.15 (± 58.654)	32.73 (± 53.286)	
Day 85: 240 min, 12, 12, 11	0.5 (± 32.609)	0 (± 31.955)	9.82 (± 69.417)	

Notes:

[64] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[65] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[66] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in C-peptide levels from the post-MMT (MMT) at pre-meal and 15, 30, 60, 90, 120, 180, and 250 minutes post-meal at Days 29, 57, and 85

End point title	Change from Baseline in C-peptide levels from the post-MMT (MMT) at pre-meal and 15, 30, 60, 90, 120, 180, and 250 minutes post-meal at Days 29, 57, and 85

End point description:

The Baseline C-peptide value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary

End point timeframe:

Baseline; pre-meal; and 15, 30, 60, 90, 120, 180, and 250 post-meal at Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[67]	13[68]	12[69]	
Units: Nanomoles per liter				
arithmetic mean (standard deviation)				
Day 29: pre-meal, n=12, 12, 11	0 (± 0.342)	0.13 (± 0.307)	0.07 (± 0.45)	
Day 29: 15 min, n=12, 12, 11	0.34 (± 0.436)	0.45 (± 0.397)	0.51 (± 0.757)	
Day 29: 30 min, n=12, 12, 10	0.68 (± 0.595)	0.89 (± 0.634)	0.92 (± 0.86)	

Day 29: 60 min, n=11, 12, 11	1.14 (± 0.617)	1.08 (± 0.693)	1.33 (± 0.97)	
Day 29: 90 min, n=11, 12, 11	1.05 (± 0.284)	1.15 (± 0.573)	1.11 (± 0.844)	
Day 29: 120 min, n=11, 12, 10	0.92 (± 0.37)	1.09 (± 0.527)	1.03 (± 0.672)	
Day 29: 180 min, n=12, 12, 10	0.81 (± 0.438)	0.6 (± 0.323)	0.59 (± 0.46)	
Day 29: 240 min, n=12, 12, 11	0.5 (± 0.463)	0.27 (± 0.329)	0.31 (± 0.355)	
Day 57: pre-meal, n=12, 12, 12	-0.07 (± 0.314)	0.07 (± 0.341)	-0.23 (± 0.244)	
Day 57: 15 min, n=12, 12, 11	0.21 (± 0.213)	0.61 (± 0.941)	0.29 (± 0.349)	
Day 57: 30 min n=12, 12, 11	0.56 (± 0.369)	0.85 (± 0.973)	0.45 (± 0.543)	
Day 57: 60 min, n=12, 12, 11	1.04 (± 0.591)	1.25 (± 0.583)	0.92 (± 0.821)	
Day 57: 90 min, n=12, 12, 11	1.1 (± 0.371)	1.38 (± 0.653)	1.02 (± 0.89)	
Day 57: 120 min, n=12, 12, 11	1.06 (± 0.435)	1.09 (± 0.524)	1.02 (± 0.837)	
Day 57: 180 min, n=12, 12, 11	0.59 (± 0.332)	0.6 (± 0.43)	0.53 (± 0.482)	
Day 57: 240 min, n=11, 12, 10	0.29 (± 0.48)	0.31 (± 0.395)	0.2 (± 0.41)	
Day 85: pre-meal, n=12, 12, 11	-0.01 (± 0.412)	0.09 (± 0.325)	0.02 (± 0.422)	
Day 85: 15 min, n=12, 12, 11	0.17 (± 0.413)	0.45 (± 0.475)	0.45 (± 0.721)	
Day 85: 30 min, n=12, 12, 11	0.78 (± 0.832)	0.98 (± 0.725)	0.65 (± 0.742)	
Day 85: 60 min, n=12, 12, 11	0.96 (± 0.518)	1.38 (± 0.683)	1.03 (± 0.624)	
Day 85: 90 min, n=12, 12, 11	1.01 (± 0.499)	1.48 (± 0.738)	1.11 (± 0.55)	
Day 85: 120 min, n=12, 12, 11	1.05 (± 0.404)	1.43 (± 0.856)	1.08 (± 0.566)	
Day 85: 180 min, n=11, 12, 11	0.6 (± 0.427)	0.75 (± 0.436)	0.6 (± 0.361)	
Day 85: 240 min, n=12, 12, 10	0.28 (± 0.358)	0.33 (± 0.234)	0.26 (± 0.416)	

Notes:

[67] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[68] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[69] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in weighted mean insulin level (AUC[0-4hrs]) post-MMT on Days 29, 57, and 85

End point title	Change from Baseline in weighted mean insulin level (AUC[0-4hrs]) post-MMT on Days 29, 57, and 85

End point description:

The weighted mean parameters were derived by calculating the area under the curve (AUC, which reflects the actual body exposure to drug after administration of a dose of the drug) using the trapezoidal rule, and then dividing by the actual relevant time interval (i.e., actual time point [hrs] of the first non-missing observation [in planned time tf=0 hour] minus the actual time point [hrs] of the last non-missing observation [e.g., in planned time for insulin, tl=240 minutes]). Change from Baseline in weighted mean AUC(0-4hrs) post-MMT profiles for insulin was compared between treatment groups using repeated measures analysis with fixed effects for Baseline, visit, and Baseline by visit. The Baseline weighted mean insulin value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[70]	13[71]	12[72]	
Units: Picomoles per liter				
arithmetic mean (standard deviation)				
Day 29	10.3 (± 39.145)	-1.13 (± 103.423)	4.89 (± 68.334)	
Day 57	12.52 (± 56.021)	-2.11 (± 56.314)	21.55 (± 68.549)	
Day 85	12.26 (± 37.965)	13.16 (± 78.556)	9.14 (± 61.995)	

Notes:

[70] - All Subject Population

[71] - All Subject Population

[72] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in weighted mean C-peptide levels (AUC[0-4hrs]) post-MMT on Days 29, 57, and 85

End point title	Change from Baseline in weighted mean C-peptide levels (AUC[0-4hrs]) post-MMT on Days 29, 57, and 85

End point description:

The weighted mean parameters were derived by calculating the area under the curve (AUC, which reflects the actual body exposure to drug after administration of a dose of the drug) using the trapezoidal rule, and then dividing by the actual relevant time interval (i.e., actual time point [hrs] of the first non-missing observation [in planned time tf=0 hour] minus the actual time point [hrs] of the last non-missing observation [e.g., in planned time for C-peptide levels, tl=240 minutes]). Change from Baseline in weighted mean AUC(0-4hrs) post-MMT profiles for C-peptide was compared between treatment groups using repeated measures analysis with fixed effects for Baseline, visit, and Baseline by visit. The Baseline weighted mean C-peptide value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[73]	13[74]	12[75]	
Units: Nanomoles per liter (nmol/L)				
arithmetic mean (standard deviation)				
Day 29	0.19 (± 0.365)	-0.1 (± 0.302)	-0.09 (± 0.592)	
Day 57	0.1 (± 0.234)	-0.06 (± 0.327)	-0.24 (± 0.661)	
Day 85	0.1 (± 0.247)	0.09 (± 0.374)	-0.16 (± 0.521)	

Notes:

[73] - All Subject Population

[74] - All Subject Population

[75] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in derived measures of insulin sensitivity (homeostasis model assessment [HOMA]-%S) and beta cell function (HOMA-%B) for insulin and C-peptide at Days 29, 57, and 85

End point title	Change from Baseline in derived measures of insulin sensitivity (homeostasis model assessment [HOMA]-%S) and beta cell function (HOMA-%B) for insulin and C-peptide at Days 29, 57, and 85

End point description:

The HOMA estimated steady-state beta cell function (%B) and insulin sensitivity (%S), as a percentages of a normal reference population. The HOMA2 Model was developed for insulin sensitivity (HOMA2-%S), where 100% was normal, which is the reciprocal of insulin resistance (100/S%). The Baseline value is defined as the value at Day 1. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. Note: In cases in which no participants were analyzed at a particular timepoint/for a paricular parameter, "99999" is used to indicate that data are not available. In cases, in which only one participant was analyzed at a particular timepoint/for a particular parameter, "99999" has been used to indicate that no dispersion data (standard deviation of the mean) are available for this single participant.

End point type	Secondary

End point timeframe:

Baseline; Days 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[76]	13[77]	12[78]	
Units: Percentage				
arithmetic mean (standard deviation)				
Insulin HOMA2-%S, Day 29, n=12, 12, 12	9.42 (± 35.88)	-10.03 (± 29.411)	-5.33 (± 27.589)	
Insulin HOMA2-%S, Day 57, n=12, 12, 12	0.39 (± 12.438)	-8.21 (± 41.853)	4.45 (± 33.226)	
Insulin HOMA2-%S, Day 85, n=12, 12, 11	-3 (± 15.088)	-15.46 (± 54.893)	-6.81 (± 28.723)	
Insulin HOMA2-%B, Day 29, n=12, 12, 12	-1.82 (± 12.091)	5.42 (± 10.715)	3.31 (± 18.961)	
Insulin HOMA2-%B, Day 57, n=12, 12, 12	5.9 (± 21.891)	6.63 (± 18.161)	7.5 (± 31.909)	
Insulin HOMA2-%B, Day 85, n=12, 12, 11	4.24 (± 23.204)	7.77 (± 24.274)	7.45 (± 29.459)	
C-peptide, HOMA2-%S, Day 29, n=0, 1, 0	99999 (± 99999)	-4.6 (± 99999)	99999 (± 99999)	
C-peptide, HOMA2-%S, Day 57, n=0, 1, 0	99999 (± 99999)	-3.8 (± 99999)	99999 (± 99999)	
C-peptide, HOMA2-%S, Day 85, n=0, 1, 0	99999 (± 99999)	-1.8 (± 99999)	99999 (± 99999)	

C-peptide, HOMA2-%B, Day 29, n=0, 1, 0	99999 (± 99999)	33.7 (± 99999)	99999 (± 99999)	
C-peptide, HOMA2-%B, Day 57, n=0, 1, 0	99999 (± 99999)	20 (± 99999)	99999 (± 99999)	
C-peptide, HOMA2-%B, Day 85, n=0, 1, 0	99999 (± 99999)	-33.5 (± 99999)	99999 (± 99999)	

Notes:

[76] - All Subject Population

[77] - All Subject Population

[78] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve over the dosing interval (AUC[0-tau])

End point title	Area under the concentration-time curve over the dosing interval (AUC[0-tau])

End point description:

AUC(0-tau) is derived as a log-transformed plasma GSK1070806 pharmacokinetic (PK) Parameter and was measured after dose 1 and dose 2 of GSK1070806 0.25 mg/kg and GSK1070806 5 mg/kg. AUC reflects the actual body exposure to drug after administration of a dose of the drug. The PK Population is comprised of participants for whom a PK sample was obtained and analyzed.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[79]	13[80]	12[81]	
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)				
Dose 1, n=0, 11, 12	()	1840725 (± 32.5)	25415627 (± 62.5)	
Dose 2, n=0, 13, 12	()	2483463 (± 31.3)	44281604 (± 22.8)	

Notes:

[79] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[80] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[81] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed concentration (Cmax)

End point title	Maximum observed concentration (Cmax)

End point description:

Cmax was measured after dose 1 and dose 2 of GSK1070806 0.25 mg/kg and GSK1070806 5 mg/kg.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210/average of X study days)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[82]	13[83]	12[84]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Dose 1, n=0, 11, 12	()	8361.1 (± 26.8)	95179.3 (± 69)	
Dose 2, n=0, 13, 12	()	9692.1 (± 21.9)	152972 (± 22)	

Notes:

[82] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[83] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[84] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Time of occurrence of Cmax (Tmax)

End point title	Time of occurrence of Cmax (Tmax)

End point description:

Tmax was measured after dose 1 and dose 2 of GSK1070806 0.25 mg/kg and GSK1070806 5 mg/kg.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210/average of X study days)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[85]	13[86]	12[87]	
Units: Hours				
median (full range (min-max))				
Dose 1, n=0, 11, 12	(to)	1.05 (1 to 67.75)	1.055 (1 to 4.03)	
Dose 2, n=0, 13, 12	(to)	1.07 (1 to 68.5)	1.05 (1 to 4)	

Notes:

[85] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[86] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

[87] - PK Population. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal phase rate constant

End point title	Terminal phase rate constant

End point description:

The terminal rate constant is the rate at which the compound disappears more slowly during the terminal phase. The terminal phase rate constant was measured after the second dose of GSK1070806 0.25 mg/kg and GSK1070806 5 mg/kg. Summary statistics are not generated for this parameter as it is utilized for the calculation of other parameters.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[88]	0[89]	0[90]	
Units: 1/hr				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[88] - PK Population

[89] - PK Population

[90] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal half life (t1/2)

End point title	Terminal half life (t1/2)

End point description:

t1/2 was measured after the second dose of GSK1070806 0.25 mg/kg and GSK1070806 5 mg/kg.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[91]	12[92]	12[93]	
Units: Hours				
geometric mean (geometric coefficient of variation)	()	554.721 (± 22.7)	730.386 (± 21.3)	

Notes:

[91] - PK Population. Only participants available at the specified time points were analyzed.

[92] - PK Population. Only participants available at the specified time points were analyzed.

[93] - PK Population. Only participants available at the specified time points were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum levels of free IL-18 and drug-bound IL-18

End point title	Serum levels of free IL-18 and drug-bound IL-18

End point description:

Summary statistics were not generated for this parameter.

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[94]	0[95]	0[96]	
Units: picograms per milliliter (pg/ml)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[94] - Summary statistics were not generated for this parameter.

[95] - Summary statistics were not generated for this parameter.

[96] - Summary statistics were not generated for this parameter.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in adiponectin and high-sensitivity C-reactive protein (hsCRP) levels at Days 29, 57, and 85

End point title	Change from Baseline in adiponectin and high-sensitivity C-reactive protein (hsCRP) levels at Days 29, 57, and 85

End point description:

Serum samples were collected for the estimation of adiponectin and hsCRP biomarker levels. Adiponectin is a protein hormone that modulates a number of metabolic processes, including glucose regulation and fatty acid catabolism. Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Day 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[97]	13[98]	12[99]	
Units: mg/L				
arithmetic mean (standard deviation)				
Adiponectin, Day 29, n=12, 13, 12	0.08 (± 2.021)	-0.62 (± 2.567)	-1.58 (± 5.534)	
Adiponectin, Day 57, n=12, 13, 12	-0.08 (± 2.275)	-0.54 (± 2.933)	0.25 (± 2.896)	
Adiponectin, Day 85, n=12, 13, 12	0.67 (± 1.875)	0 (± 2.236)	0.42 (± 1.621)	
hsCRP, Day 29, n=12, 11, 12	3.04 (± 6.577)	13.96 (± 49.633)	-8.08 (± 20.237)	
hsCRP, Day 57, n=12, 11, 12	3.47 (± 7.662)	-0.55 (± 1.226)	-8.1 (± 19.414)	
hsCRP, Day 85, n=12, 11, 12	0.54 (± 2.137)	-0.17 (± 2.311)	-8.06 (± 19.995)	

Notes:

[97] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[98] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[99] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HDL cholesterol, LDL cholesterol, and non-esterified fatty acid levels at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Change from Baseline in HDL cholesterol, LDL cholesterol, and non-esterified fatty acid levels at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Serum samples were collected for the estimation of HDL cholesterol direct, LDL cholesterol calculation, and non-esterified fatty acids biomarker levels. Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[100]	13[101]	12[102]	
Units: mmol/L				
arithmetic mean (standard deviation)				
HDL cholesterol, Day 1: 4 hr, n=11, 11, 11	-0.1 (± 0.096)	-0.1 (± 0.116)	-0.11 (± 0.07)	
HDL cholesterol, Day 4, n=11, 12, 11	0.07 (± 0.074)	0.01 (± 0.077)	0.02 (± 0.119)	
HDL cholesterol, Day 9, n=12, 12, 12	0.06 (± 0.117)	0.05 (± 0.134)	0.06 (± 0.087)	
HDL cholesterol, Day 14, n=12, 12, 12	0.04 (± 0.118)	0.06 (± 0.121)	0.1 (± 0.116)	
HDL cholesterol, Day 21, n=12, 12, 12	0.07 (± 0.153)	0.09 (± 0.146)	0.12 (± 0.215)	

HDL cholesterol, Day 29 pre-dose, n=11, 12, 12	-0.01 (± 0.13)	0.04 (± 0.106)	0.12 (± 0.197)	
HDL cholesterol, Day 29: 4 hr, n=12, 10, 11	-0.1 (± 0.134)	-0.01 (± 0.154)	0.01 (± 0.216)	
HDL cholesterol, Day 32, n=11, 12, 12	0.06 (± 0.174)	0.05 (± 0.145)	0.1 (± 0.129)	
HDL cholesterol, Day 42, n=12, 12, 12	0.06 (± 0.167)	0.06 (± 0.122)	0.12 (± 0.204)	
HDL cholesterol, Day 57, n=12, 12, 12	0.02 (± 0.114)	0.08 (± 0.204)	0.12 (± 0.207)	
HDL cholesterol, Day 85, n=11, 11, 12	0.03 (± 0.19)	0.08 (± 0.19)	0.12 (± 0.195)	
HDL cholesterol, Day 120, n=11, 12, 12	0.04 (± 0.164)	0.12 (± 0.228)	0.12 (± 0.211)	
HDL cholesterol, Day 165, n=12, 11, 12	0.05 (± 0.191)	0.12 (± 0.171)	0.09 (± 0.123)	
HDL cholesterol, follow-up, n=12, 11, 12	0.13 (± 0.161)	0.09 (± 0.171)	0.07 (± 0.129)	
LDL cholesterol, Day 1: 4 hr, n=11, 11, 10	-0.35 (± 0.217)	-0.36 (± 0.351)	-0.23 (± 0.159)	
LDL cholesterol, Day 4, n=11, 12, 11	0.02 (± 0.268)	0.1 (± 0.226)	0.06 (± 0.28)	
LDL cholesterol, Day 9, n=12, 12, 12	-0.06 (± 0.426)	-0.08 (± 0.342)	-0.12 (± 0.274)	
LDL cholesterol, Day 14, n=12, 12, 12	-0.09 (± 0.564)	-0.09 (± 0.35)	-0.08 (± 0.391)	
LDL cholesterol, Day 21, n=12, 12, 12	-0.01 (± 0.58)	0.02 (± 0.506)	-0.1 (± 0.394)	
LDL cholesterol, Day 29 pre-dose, n=11, 12, 12	-0.05 (± 0.389)	-0.06 (± 0.484)	-0.04 (± 0.413)	
LDL cholesterol, Day 29: 4 hr, n=12, 10, 11	-0.36 (± 0.508)	-0.37 (± 0.583)	-0.39 (± 0.611)	
LDL cholesterol, Day 32, n=11, 12, 12	-0.01 (± 0.553)	-0.16 (± 0.379)	0.02 (± 0.3)	
LDL cholesterol, Day 42, n=11, 12, 12	0.2 (± 0.357)	-0.1 (± 0.542)	0 (± 0.325)	
LDL cholesterol, Day 57, n=12, 12, 12	0.23 (± 0.542)	-0.08 (± 0.356)	0.13 (± 0.407)	
LDL cholesterol, Day 85, n=11, 11, 12	0.25 (± 0.784)	0.02 (± 0.406)	0.02 (± 0.507)	
LDL cholesterol, Day 120, n=10, 12, 12	0.14 (± 0.493)	-0.14 (± 0.61)	0.07 (± 0.475)	
LDL cholesterol, Day 165, n=12, 11, 12	0.2 (± 0.836)	-0.1 (± 0.624)	0.15 (± 0.613)	
LDL cholesterol, follow-up, n=12, 11, 12	0.31 (± 0.844)	0.13 (± 0.417)	-0.2 (± 0.967)	
Non-esterfied fatty acids, Day 29, n=12, 13, 10	-0.04 (± 0.135)	-0.02 (± 0.177)	0.01 (± 0.277)	
Non-esterfied fatty acids, Day 57, n=12, 13, 10	0.04 (± 0.212)	0.07 (± 0.189)	0.06 (± 0.311)	
Non-esterfied fatty acids, Day 85, n=12, 13, 10	-0.01 (± 0.144)	0.02 (± 0.187)	-0.05 (± 0.35)	

Notes:

[100] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[101] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[102] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in fructosamine level at Days 29, 57, and 85

End point title	Change from Baseline in fructosamine level at Days 29, 57, and 85

End point description:

Serum samples were collected for the estimation of fructosamine levels. Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Day 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11[103]	12[104]	10[105]	
Units: µmol/L				
arithmetic mean (standard deviation)				
Day 29	-7.36 (± 25.26)	-10.25 (± 18.489)	-9 (± 19.402)	
Day 57	-4.18 (± 45.751)	-10.17 (± 30.68)	-6.7 (± 23.66)	
Day 85	-1 (± 43.428)	-6.83 (± 23.053)	-8.1 (± 29.622)	

Notes:

[103] - All Subject Population. Only participants available at the specified time points were analyzed.

[104] - All Subject Population. Only participants available at the specified time points were analyzed.

[105] - All Subject Population. Only participants available at the specified time points were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in glomerular filtration rate (GFR) at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Change from Baseline in glomerular filtration rate (GFR) at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[106]	13[107]	12[108]	
Units: mL/min/1.73 m^2				
arithmetic mean (standard deviation)				
Day 1: 4 hr, n=11, 10, 11	-1.18 (± 14.972)	-24.4 (± 19.693)	-18.45 (± 24.411)	
Day 4, n=11, 12, 11	-10.55 (± 13.419)	-12.5 (± 11.39)	-4.18 (± 10.196)	
Day 9, n=12, 12, 12	-8.33 (± 11.484)	-10.83 (± 10.911)	-8.17 (± 12.597)	
Day 14, n=12, 12, 12	-8.5 (± 11.642)	-16.75 (± 10.593)	-4.08 (± 9.307)	

Day 21, n=12, 12, 12	-8.5 (± 12.147)	-14 (± 10.796)	-7.67 (± 13.68)	
Day 29 pre-dose, n=11, 12, 12	-3 (± 12.61)	-4.5 (± 12.236)	-0.75 (± 13.844)	
Day 29: 4 hr, n=12, 9, 11	-9.92 (± 14.494)	-25.89 (± 20.521)	-15.18 (± 21.706)	
Day 32, n=11, 12, 12	-4.64 (± 11.227)	-19.92 (± 8.49)	-3.08 (± 16.082)	
Day 42, n=12, 12, 12	-9.5 (± 12.895)	-16.83 (± 10.223)	-9.42 (± 15.359)	
Day 57, n=12, 12, 12	-8.5 (± 9.968)	-5.08 (± 10.149)	-2.33 (± 11.284)	
Day 85, n=12, 11, 12	-7.75 (± 8.508)	-14.18 (± 9.453)	-5.17 (± 16.297)	
Day 120, n=11, 12, 12	-11.73 (± 13.001)	-17 (± 13.981)	-11.5 (± 17.578)	
Day 165, n=12, 11, 12	-14.58 (± 12.831)	-10.91 (± 13.262)	-9.08 (± 14.669)	
Follow-up, n=12, 11, 12	-13.5 (± 10.975)	-11.91 (± 11.97)	-12.5 (± 17.381)	

Notes:

[106] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[107] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[108] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in interleukin-6 (IL-6), inducible protein-10 (IP-10), matrix metalloproteinase-9 (MMP-9), intercellular adhesion molecule-1 (IAM-1), and plasminogen activator inhibitor-1 (PAI-1) levels at Days 29, 57, and 85

End point title	Change from Baseline in interleukin-6 (IL-6), inducible protein-10 (IP-10), matrix metalloproteinase-9 (MMP-9), intercellular adhesion molecule-1 (IAM-1), and plasminogen activator inhibitor-1 (PAI-1) levels at Days 29, 57, and 85

End point description:

Serum samples were collected to estimate IL-6, IP-10, MMP-9, IAM-1 levels, and plasma samples were collected for the estimation of PAI-1. Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Day 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[109]	13[110]	12[111]	
Units: ng/L				
arithmetic mean (standard deviation)				
IL-6, Day 29	0.83 (± 2.392)	0.57 (± 2.149)	-1.03 (± 3.034)	
IL-6, Day 57	-0.24 (± 0.934)	0.42 (± 0.959)	-1.21 (± 2.71)	

IL-6, Day 85	-0.04 (± 1.362)	-0.17 (± 1.002)	-0.93 (± 2.819)	
Inducible protein 10, Day 29	9.34 (± 153.643)	25.93 (± 137.181)	-71.82 (± 109.09)	
Inducible protein 10, Day 57	-39.36 (± 122.103)	5.75 (± 135.903)	-57.63 (± 122.93)	
Inducible protein 10, Day 85	-1.29 (± 92.374)	-4.61 (± 115.887)	-80.62 (± 100.406)	
MMP-9, Day 29	-90583.7 (± 237918.2)	-12523.3 (± 292929)	-155023 (± 295290.1)	
MMP-9, Day 57	-13157.9 (± 261712.8)	-83140.8 (± 124294.1)	-108312 (± 315259.2)	
MMP-9, Day 85	11328.1 (± 148277.1)	33993.3 (± 272533.5)	-143274 (± 324839.2)	
PAI-1, Day 29	32889.5 (± 56971.2)	2692 (± 65526.9)	-15486.5 (± 37095.97)	
PAI-1, Day 57	14470.7 (± 39216.4)	5161.77 (± 55823.3)	-14603.6 (± 88836.85)	
PAI-1, Day 85	13992.3 (± 38433.2)	24970.6 (± 96291.6)	-14082.4 (± 75656.88)	
IAM-1, Day 29	-648.1 (± 100568.4)	15984.15 (± 109324.5)	-18708.7 (± 67939.63)	
IAM-1, Day 57	-31678.9 (± 114736.3)	21330.63 (± 137433.9)	-36358.3 (± 99707.46)	
IAM-1, Day 85	-60516.9 (± 120963.1)	-1197.05 (± 78516.41)	-75448.8 (± 101530.3)	

Notes:

[109] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[110] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[111] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in lymphocytes biomarker levels at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point title	Change from Baseline in lymphocytes biomarker levels at Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up

End point description:

Change from Baseline is defined as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Days 1 (4 hr post-dose), 4, 9, 14, 21, 29 (pre-dose and 4 hr post-dose), 32, 42, 57, 85, 120, and 165; and follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[112]	13[113]	12[114]	
Units: GI/L				
arithmetic mean (standard deviation)				
Day 1: 4 hr, n=12, 12, 10	0.18 (± 0.311)	0.28 (± 0.357)	0.36 (± 0.436)	
Day 4, n=11, 12, 10	0.24 (± 0.403)	0.17 (± 0.281)	0.31 (± 0.487)	
Day 9, n=12, 13, 11	0.26 (± 0.364)	0.25 (± 0.324)	0.33 (± 0.734)	
Day 14, n=12, 12, 11	0.18 (± 0.599)	0.16 (± 0.43)	0.31 (± 0.951)	
Day 21, n=12, 13, 11	0.1 (± 0.429)	0.22 (± 0.359)	0.44 (± 0.541)	
Day 29 pre-dose, n=12, 13, 11	-0.05 (± 0.458)	-0.05 (± 0.421)	0.03 (± 0.365)	
Day 29: 4 hr, n=12, 13, 11	0.19 (± 0.467)	0.45 (± 0.582)	0.4 (± 0.579)	
Day 32, n=12, 13, 9	0.09 (± 0.498)	0.1 (± 0.532)	0.44 (± 0.269)	
Day 42, n=12, 13, 11	-0.06 (± 0.528)	0.06 (± 0.276)	0.29 (± 0.553)	
Day 57, n=12, 13, 11	0.16 (± 0.549)	0.21 (± 0.269)	0.28 (± 0.496)	
Day 85, n=12, 13, 11	-0.02 (± 0.497)	0.13 (± 0.319)	0.25 (± 0.536)	
Day 120, n=10, 13, 11	0.22 (± 0.394)	0.12 (± 0.377)	0.27 (± 0.448)	
Day 165, n=12, 13, 11	0.14 (± 0.602)	0.28 (± 0.304)	0.47 (± 0.712)	
Follow-up, n=12, 13, 11	0.14 (± 0.478)	0.18 (± 0.359)	0.27 (± 0.649)	

Notes:

[112] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[113] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[114] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in resistin biomarker levels at Days 29, 57, and 85

End point title	Change from Baseline in resistin biomarker levels at Days 29, 57, and 85

End point description:

Serum samples were collected to estimate resistin levels. Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Day 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[115]	13[116]	11[117]	
Units: micrograms per liter (µg/L)				
arithmetic mean (standard deviation)				
Day 29	-0.17 (± 3.114)	-0.03 (± 2.045)	-2.22 (± 2.127)	
Day 57	-0.6 (± 1.67)	-0.23 (± 1.383)	-0.36 (± 2.071)	

Day 85	1.44 (± 4.065)	0.22 (± 1.308)	-0.45 (± 2.07)	

Notes:

[115] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[116] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[117] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Albumin/Creatinine Ratio, MCP1/Creatinine Ratio, and HDL/LDL Ratio at Days 29, 57, and 85

End point title	Change from Baseline in Albumin/Creatinine Ratio, MCP1/Creatinine Ratio, and HDL/LDL Ratio at Days 29, 57, and 85

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value, where Day 1 is defined as Baseline.

End point type	Secondary

End point timeframe:

Baseline; Day 29, 57, and 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[118]	13[119]	12[120]	
Units: Ratio				
arithmetic mean (standard deviation)				
Albumin/Creatinine Ratio, Day 29, n=11, 13, 9	-21.55 (± 44.239)	-14.88 (± 34.18)	-3.65 (± 9.827)	
Albumin/Creatinine Ratio, Day 57, n=12, 13, 10	-20 (± 49.537)	-13.89 (± 41.526)	5.49 (± 12.835)	
Albumin/Creatinine Ratio, Day 85, n=12, 13, 11	-16.1 (± 36.231)	-15.68 (± 38.938)	1.94 (± 12.017)	
MCP1/Creatinine Ratio, Day 29, n=11, 13, 9	9.07 (± 22.821)	-21.78 (± 32.329)	-1.02 (± 25.843)	
MCP1/Creatinine Ratio, Day 57, n=12, 13, 11	2.81 (± 15.518)	-1.4 (± 28.885)	0.91 (± 18.641)	
MCP1/Creatinine Ratio, Day 85, n=12, 12, 11	-4.48 (± 18.868)	-17.13 (± 11.408)	0.37 (± 21.605)	
HDL/LDL ratio, Day 1:4H, n=11, 11, 10	0.07 (± 0.088)	0.01 (± 0.044)	0 (± 0.052)	
HDL/LDL ratio, Day 4, n=11, 12, 11	0.01 (± 0.063)	-0.02 (± 0.029)	-0.01 (± 0.068)	
HDL/LDL ratio, Day 9, n=12, 12, 12	0.01 (± 0.084)	0.04 (± 0.039)	0.08 (± 0.131)	
HDL/LDL ratio, Day 14, n=12, 12, 12	0.01 (± 0.116)	0.03 (± 0.051)	0.04 (± 0.12)	
HDL/LDL ratio, Day 21, n=12, 12, 12	0.01 (± 0.107)	0.03 (± 0.065)	0.04 (± 0.114)	
HDL/LDL ratio, Day 29 predose, n=11, 12, 12	0.03 (± 0.091)	0.04 (± 0.067)	0.04 (± 0.11)	
HDL/LDL ratio, Day 29:4H, n=12, 10, 11	0.08 (± 0.124)	0.08 (± 0.087)	0.1 (± 0.174)	
HDL/LDL ratio, Day 32, n=11, 12, 12	0 (± 0.131)	0.05 (± 0.05)	0.02 (± 0.118)	
HDL/LDL ratio, Day 42, n=11, 12, 12	-0.02 (± 0.062)	0.04 (± 0.072)	0.03 (± 0.118)	

HDL/LDL ratio, Day 57, n=12, 12, 12	-0.05 (± 0.104)	0.05 (± 0.099)	0.09 (± 0.223)	
HDL/LDL ratio, Day 85, n=11, 11, 12	-0.02 (± 0.079)	0.03 (± 0.072)	0.07 (± 0.159)	
HDL/LDL ratio, Day 120, n=10, 12, 12	-0.03 (± 0.126)	0.08 (± 0.078)	0.04 (± 0.095)	
HDL/LDL ratio, Day 165, n=12, 11, 12	0.02 (± 0.097)	0.05 (± 0.08)	0.05 (± 0.246)	
HDL/LDL ratio, follow-up, n=12, 11, 12	0.01 (± 0.095)	0.01 (± 0.068)	0.1 (± 0.189)	

Notes:

[118] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[119] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

[120] - ASP. Only participants available at the specified time points were analyzed (n=X, X, X).

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in waist circumference at Day 85

End point title	Change from Baseline in waist circumference at Day 85

End point description:

Summary statistics were not generated for these parameters.

End point type	Secondary

End point timeframe:

Baseline; Day 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[121]	0[122]	0[123]	
Units: centimeters				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[121] - All Subject Population

[122] - All Subject Population

[123] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with detectable levels of anti-GSK1070806 antibodies

End point title	Number of participants with detectable levels of anti-GSK1070806 antibodies

End point description:

End point type	Secondary

End point timeframe:

From Day 1 until follow-up (up to Study Day 210)

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[124]	13[125]	12[126]	
Units: participants		0	0	

Notes:

[124] - All Subject Population

[125] - All Subject Population

[126] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in body mass index (BMI) at Day 85

End point title	Change from Baseline in body mass index (BMI) at Day 85

End point description:

End point type	Secondary

End point timeframe:

Baseline; Day 85

End point values	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[127]	0[128]	0[129]	
Units: kilograms per meters squared (kg/m^2)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[127] - All Subject Population

[128] - All Subject Population

[129] - All Subject Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from the start of study treatment until follow-up (assessed up to Study Day 210).

Adverse event reporting additional description:

SAEs and non-serious AEs are reported for members of the All Subject Population, comprised of all participants who received study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received placebo via intravenous (IV) infusion on the Day 1 and Day 29 study visits.

Reporting group title	GSK1070806 0.25 mg/kg

Reporting group description:

Participants received GSK1070806 0.25 milligrams per kilogram (mg/kg) via IV infusion on the Day 1 and Day 29 study visits.

Reporting group title	GSK1070806 5 mg/kg

Reporting group description:

Participants received GSK1070806 5 mg/kg via IV infusion on the Day 1 and Day 29 study visits.

Serious adverse events	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	1 / 12 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
VIIth nerve paralysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diverticulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	GSK1070806 0.25 mg/kg	GSK1070806 5 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 12 (83.33%)	12 / 13 (92.31%)	11 / 12 (91.67%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	3 / 12 (25.00%)
occurrences (all)	0	2	3
Aortic stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Arterial disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Male sexual dysfunction			

subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Acute respiratory failure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nasal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Anxiety			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Muscle rupture			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0

Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	3 / 13 (23.08%)	1 / 12 (8.33%)
occurrences (all)	1	4	1
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	3 / 13 (23.08%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Paraesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Amnesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Loss of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 12 (16.67%)	1 / 13 (7.69%)	2 / 12 (16.67%)
occurrences (all)	2	2	2
Toothache			
subjects affected / exposed	2 / 12 (16.67%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	3	1	0

Constipation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Dermatitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hangnail			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Ingrowing nail			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	2 / 12 (16.67%)
occurrences (all)	0	2	3
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	3
Lumbar spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Muscle contracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 12 (33.33%)	3 / 13 (23.08%)	4 / 12 (33.33%)
occurrences (all)	5	4	8
Urinary tract infection			

subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Acute tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			

Gout subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0	1 / 12 (8.33%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported