Clinical trial results:
A Randomized, Double-Blind (Sponsor-unblinded), Placebo-Controlled, Adaptive Trial to Investigate the Antiviral Effect, Safety, Tolerability and Pharmacokinetics of GSK3640254 in HIV-1 Infected Treatment-Naïve Adults

Summary

EudraCT number	2018-002208-15
Trial protocol	FR ES IT
Global end of trial date	06 February 2020

Results information

Result version number	v1 (current)
This version publication date	12 February 2021
First version publication date	12 February 2021

Trial information

Trial identification

Sponsor protocol code	208132

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com

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	28 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the antiviral activity of GSK3640254 in HIV-1-infected participants during 10 days of monotherapy

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 January 2019
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	France: 4
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Spain: 21
Worldwide total number of subjects	34
EEA total number of subjects	31

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)	34
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a randomized, double-blind, placebo-controlled, adaptive clinical trial to evaluate the antiviral effect, safety, tolerability and pharmacokinetic (PK)/pharmacodynamics (PD) of GSK3640254 over 10 days in study Part 1 and over 7 days in study Part 2.

Pre-assignment

Screening details:

A total of 34 participants (14 participants in Part 1 and 20 participants in Part 2) were enrolled in this study. This study was conducted in France, Germany, Italy, South Africa and Spain.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: GSK3640254 10 mg

Arm description:

Participants received GSK3640254 10 milligram (mg), capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Arm type	Experimental
Investigational medicinal product name	GSK3640254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

GSK3640254 was available as capsules at unit dose strength of 5, 20 and 100 milligrams (mg) to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal

Arm title	Part 1: GSK3640254 200 mg

Arm description:

Participants received GSK3640254 200 mg, capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Arm type	Experimental
Investigational medicinal product name	GSK3640254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

GSK3640254 was available as capsules at unit dose strength of 5, 20 and 100 milligrams (mg) to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal

Arm title	Part 1: Placebo

Arm description:

Participants received placebo capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was available as capsules to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal.

Arm title	Part 2: GSK3640254 40 mg

Arm description:

Participants received GSK3640254 40 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Arm type	Experimental
Investigational medicinal product name	GSK3640254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

GSK3640254 was available as capsules at unit dose strength of 5, 20 and 100 milligrams (mg) to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal

Arm title	Part 2: GSK3640254 80 mg

Arm description:

Participants received GSK3640254 80 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Arm type	Experimental
Investigational medicinal product name	GSK3640254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

GSK3640254 was available as capsules at unit dose strength of 5, 20 and 100 milligrams (mg) to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal

Arm title	Part 2: GSK3640254 140 mg

Arm description:

Participants received GSK3640254 140 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Arm type	Experimental
Investigational medicinal product name	GSK3640254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

GSK3640254 was available as capsules at unit dose strength of 5, 20 and 100 milligrams (mg) to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal

Arm title	Part 2: Placebo

Arm description:

Participants received placebo capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was available as capsules to be administered orally with 240 milliliters of water following ingestion of a moderate calorie and fat meal.

Number of subjects in period 1	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo
Started	6	6	2
Completed	6	6	2

Number of subjects in period 1	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg
Started	6	6	6
Completed	6	6	6

Number of subjects in period 1	Part 2: Placebo
Started	2
Completed	2

Baseline characteristics

Reporting groups	
Reporting group title	Part 1: GSK3640254 10 mg
Reporting group description:	
Participants received GSK3640254 10 milligram (mg), capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 1: GSK3640254 200 mg
Reporting group description:	
Participants received GSK3640254 200 mg, capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 1: Placebo
Reporting group description:	
Participants received placebo capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 40 mg
Reporting group description:	
Participants received GSK3640254 40 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 80 mg
Reporting group description:	
Participants received GSK3640254 80 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 140 mg
Reporting group description:	
Participants received GSK3640254 140 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: Placebo
Reporting group description:	
Participants received placebo capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	

Reporting group values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo
Number of subjects	6	6	2
Age Categorical Units: Participants			
<=18 years	0	0	0
19-64 years	6	6	2
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Female	0	0	0
Male	6	6	2
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	2	0	0
Asian: South East Asian Heritage	1	0	0
Black or African American	0	0	0
White: White/Caucasian/European Heritage	2	5	2

Multiple: American Indian or Alaska Native & White	1	1	0

Reporting group values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg
Number of subjects	6	6	6
Age Categorical Units: Participants			
<=18 years	0	0	0
19-64 years	6	6	6
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Female	1	0	1
Male	5	6	5
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian: South East Asian Heritage	0	0	0
Black or African American	1	2	1
White: White/Caucasian/European Heritage	5	4	5
Multiple: American Indian or Alaska Native & White	0	0	0

Reporting group values	Part 2: Placebo	Total	
Number of subjects	2	34	
Age Categorical Units: Participants			
<=18 years	0	0	
19-64 years	2	34	
>=65 years	0	0	
Sex: Female, Male Units: Participants			
Female	0	2	
Male	2	32	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	3	
Asian: South East Asian Heritage	0	1	
Black or African American	0	4	
White: White/Caucasian/European Heritage	1	24	
Multiple: American Indian or Alaska Native & White	0	2	

End points

End points reporting groups

Reporting group title	Part 1: GSK3640254 10 mg
Reporting group description:	
Participants received GSK3640254 10 milligram (mg), capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 1: GSK3640254 200 mg
Reporting group description:	
Participants received GSK3640254 200 mg, capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 1: Placebo
Reporting group description:	
Participants received placebo capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 40 mg
Reporting group description:	
Participants received GSK3640254 40 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 80 mg
Reporting group description:	
Participants received GSK3640254 80 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: GSK3640254 140 mg
Reporting group description:	
Participants received GSK3640254 140 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Reporting group title	Part 2: Placebo
Reporting group description:	
Participants received placebo capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.	
Subject analysis set title	GSK3640254 10 mg to 200 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
In Part 1, participants received GSK3640254 10 mg, 200 mg, capsules, orally for 10 days and in Part 2, participants received GSK3640254 40 mg, 80 mg, 140 mg, capsules, orally for 7 days.	

Primary: Part 1: Maximum Change from Baseline in plasma Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) at Day 11

End point title	Part 1: Maximum Change from Baseline in plasma Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) at Day 11[1][2]
End point description:	
Plasma samples were collected for quantitative analysis of plasma HIV-1 RNA. A HIV-1 RNA polymerase chain reaction (PCR) assay with a lower limit of detection (LLOD) of 50 copies per milliliter was used. Baseline value was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Intent-To-Treat Exposed Population consisted of all participants who met study criteria and were enrolled into the study with documented evidence of having received at least 1 dose of treatment and at least one post-Baseline HIV-1 RNA measurement.	
End point type	Primary
End point timeframe:	
Baseline (Day 1) and Day 11	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There are no statistical data to report.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[3]	6[4]	2[5]	
Units: Copies per milliliter				
arithmetic mean (standard deviation)	-8605.8 (± 4604.40)	-100719.8 (± 89182.99)	-3406.5 (± 2591.55)	

Notes:

[3] - Intent-To-Treat Exposed Population.

[4] - Intent-To-Treat Exposed Population.

[5] - Intent-To-Treat Exposed Population.

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Maximum Change from Baseline in plasma HIV-1 RNA at Day 8

End point title	Part 2: Maximum Change from Baseline in plasma HIV-1 RNA at Day 8[6][7]

End point description:

Plasma samples were collected for quantitative analysis of plasma HIV-1 RNA. An HIV-1 RNA PCR assay with an LLOD of 50 copies per milliliter was used. Baseline value was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Primary

End point timeframe:

Baseline (Day 1) and Day 8

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There are no statistical data to report.

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[8]	6[9]	6[10]	2[11]
Units: Copies per milliliter				
arithmetic mean (standard deviation)	-48655.0 (± 26269.41)	-37904.3 (± 38814.54)	-64904.2 (± 83798.67)	-123478.5 (± 175276.92)

Notes:

[8] - Intent-To-Treat Exposed Population.

[9] - Intent-To-Treat Exposed Population.

[10] - Intent-To-Treat Exposed Population.

[11] - Intent-To-Treat Exposed Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Number of Participants with Non-Serious Adverse Events (Non-SAEs) and Serious Adverse Events (SAEs)

End point title	Part 1: Number of Participants with Non-Serious Adverse Events (Non-SAEs) and Serious Adverse Events (SAEs)[12]

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. An SAE is defined as any untoward medical occurrence that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, is a congenital anomaly/birth defect or other situations as per Medical or scientific judgment. Safety Population consisted of all participants who were enrolled into the study with documented evidence of having received at least 1 dose of randomized treatment.

End point type	Secondary

End point timeframe:

Up to Day 24

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[13]	6[14]	2[15]	
Units: Participants				
Non-SAEs	3	5	0	
SAEs	1	0	0	

Notes:

[13] - Safety Population.

[14] - Safety Population.

[15] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with Non-SAEs and SAEs

End point title	Part 2: Number of participants with Non-SAEs and SAEs[16]

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. An SAE is defined as any untoward medical occurrence that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent

disability/incapacity, is a congenital anomaly/birth defect or other situations as per Medical or scientific judgment.

End point type	Secondary

End point timeframe:

Up to Day 12

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[17]	6[18]	6[19]	2[20]
Units: Participants				
Non-SAEs	5	4	4	0
SAEs	0	0	1	0

Notes:

[17] - Safety Population.

[18] - Safety Population.

[19] - Safety Population.

[20] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count

End point title	Part 1: Change From Baseline in Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count[21]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameters: basophils, eosinophils, lymphocytes, monocytes, neutrophils, leukocytes and platelet count. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[22]	6[23]	2[24]	
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Basophils	0.005 (± 0.0266)	-0.017 (± 0.0234)	0.015 (± 0.0212)	
Eosinophils	-0.023 (± 0.1296)	0.058 (± 0.1134)	-0.025 (± 0.0212)	
Lymphocytes	-0.027 (± 0.5267)	0.458 (± 0.4412)	0.070 (± 0.0566)	
Monocytes	0.100 (± 0.1124)	-0.000 (± 0.0980)	0.055 (± 0.0212)	
Neutrophils	-0.045 (± 0.4624)	-0.525 (± 0.8169)	0.345 (± 0.1485)	
Leukocytes	0.02 (± 0.679)	-0.02 (± 1.057)	0.45 (± 0.212)	
Platelet count	25.0 (± 46.35)	11.8 (± 12.04)	13.0 (± 2.83)	

Notes:

[22] - Safety Population.

[23] - Safety Population.

[24] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Hemoglobin

End point title	Part 1: Change From Baseline in Hematology Parameter: Hemoglobin[25]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[26]	6[27]	2[28]	
Units: Grams per liter				
arithmetic mean (standard deviation)	-4.2 (± 4.96)	-1.8 (± 5.98)	-1.0 (± 5.66)	

Notes:

[26] - Safety Population.

[27] - Safety Population.

[28] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Hematocrit

End point title	Part 1: Change From Baseline in Hematology Parameter: Hematocrit[29]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: hematocrit. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[30]	6[31]	2[32]	
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)	-0.0117 (± 0.01684)	-0.0073 (± 0.01919)	-0.0010 (± 0.01838)	

Notes:

[30] - Safety Population.

[31] - Safety Population.

[32] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Erythrocytes

End point title	Part 1: Change From Baseline in Hematology Parameter: Erythrocytes[33]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[34]	6[35]	2[36]	
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)	-0.10 (± 0.190)	-0.07 (± 0.197)	0.00 (± 0.141)	

Notes:

[34] - Safety Population.

[35] - Safety Population.

[36] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Volume

End point title	Part 1: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Volume[37]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes mean corpuscular volume. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[38]	6[39]	2[40]	
Units: Femtoliter				
arithmetic mean (standard deviation)	0.0 (± 0.89)	-0.3 (± 1.03)	0.0 (± 0.00)	

Notes:

[38] - Safety Population.

[39] - Safety Population.

[40] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin

End point title	Part 1: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin[41]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes mean corpuscular hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[42]	6[43]	2[44]	
Units: Picograms				
arithmetic mean (standard deviation)	-0.08 (± 0.286)	0.03 (± 0.266)	-0.15 (± 0.071)	

Notes:

[42] - Safety Population.

[43] - Safety Population.

[44] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Hematology Parameter: Reticulocytes/Erythrocyte

End point title	Part 1: Change From Baseline in Hematology Parameter: Reticulocytes/Erythrocyte[45]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: reticulocytes/erythrocyte (erythro). Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[46]	6[47]	2[48]	
Units: Percentage of reticulocytes in erythro				
arithmetic mean (standard deviation)	0.0042 (± 0.00449)	0.0012 (± 0.00172)	0.0020 (± 0.00000)	

Notes:

[46] - Safety Population.

[47] - Safety Population.

[48] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count

End point title	Part 2: Change From Baseline in Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count[49]

End point description:

Blood samples were collected to analyze the hematology parameters: basophils, eosinophils, lymphocytes, monocytes, neutrophils, leukocytes and platelet count. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[50]	6[51]	6[52]	2[53]
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Basophils, n=5,6,5,2	0.010 (± 0.0141)	0.020 (± 0.0237)	0.022 (± 0.0084)	-0.005 (± 0.0354)
Eosinophils, n=5,6,5,2	-0.066 (± 0.2145)	-0.047 (± 0.1775)	0.034 (± 0.0404)	0.020 (± 0.0000)
Lymphocytes, n=5,6,5,2	0.006 (± 0.4458)	-0.062 (± 0.4731)	0.536 (± 0.4766)	-0.110 (± 0.2687)
Monocytes, n=5,6,5,2	-0.020 (± 0.0869)	0.022 (± 0.1705)	-0.084 (± 0.1436)	-0.130 (± 0.1131)
Neutrophils, n=5,6,5,2	0.424 (± 0.6401)	1.678 (± 2.1754)	0.432 (± 0.7007)	-0.215 (± 0.3182)
Leukocytes, n=5,6,6,2	0.34 (± 0.385)	1.62 (± 2.244)	0.52 (± 1.211)	-0.45 (± 0.071)

Platelet count, n=4,6,6,2	1.5 (± 45.82)	17.5 (± 30.26)	16.0 (± 21.57)	4.5 (± 0.71)

Notes:

[50] - Safety Population.

[51] - Safety Population.

[52] - Safety Population.

[53] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Hemoglobin

End point title	Part 2: Change From Baseline in Hematology Parameter: Hemoglobin[54]

End point description:

Blood samples were collected to analyze the hematology parameter: hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[55]	6[56]	6[57]	2[58]
Units: Grams per liter				
arithmetic mean (standard deviation)	-8.0 (± 5.10)	-4.7 (± 6.59)	-1.7 (± 7.31)	-8.0 (± 1.41)

Notes:

[55] - Safety Population.

[56] - Safety Population.

[57] - Safety Population.

[58] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Hematocrit

End point title	Part 2: Change From Baseline in Hematology Parameter: Hematocrit[59]

End point description:

Blood samples were collected to analyze the hematology parameter: hematocrit. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[60]	6[61]	6[62]	2[63]
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)	-0.0230 (± 0.01762)	-0.0123 (± 0.02096)	-0.0058 (± 0.02094)	-0.0315 (± 0.01485)

Notes:

[60] - Safety Population.

[61] - Safety Population.

[62] - Safety Population.

[63] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Erythrocytes

End point title	Part 2: Change From Baseline in Hematology Parameter: Erythrocytes[64]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[65]	6[66]	6[67]	2[68]
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)	-0.24 (± 0.207)	-0.17 (± 0.216)	-0.08 (± 0.223)	-0.30 (± 0.000)

Notes:

[65] - Safety Population.

[66] - Safety Population.

[67] - Safety Population.

[68] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Volume

End point title	Part 2: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Volume[69]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes mean corpuscular volume. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[70]	6[71]	6[72]	2[73]
Units: Femtoliter				
arithmetic mean (standard deviation)	-0.2 (± 0.45)	0.2 (± 0.98)	0.2 (± 0.98)	-2.0 (± 2.83)

Notes:

[70] - Safety Population.

[71] - Safety Population.

[72] - Safety Population.

[73] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin

End point title	Part 2: Change From Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin[74]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes mean corpuscular hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points

were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[75]	6[76]	6[77]	2[78]
Units: Picograms				
arithmetic mean (standard deviation)	-0.28 (± 0.850)	-0.05 (± 0.187)	-0.02 (± 0.337)	-0.05 (± 0.354)

Notes:

[75] - Safety Population.

[76] - Safety Population.

[77] - Safety Population.

[78] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Hematology Parameter: Reticulocytes/Erythro

End point title	Part 2: Change From Baseline in Hematology Parameter: Reticulocytes/Erythro[79]

End point description:

Blood samples were collected to analyze the hematology parameter: reticulocytes/erythro. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[79] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[80]	6[81]	6[82]	2[83]
Units: Percentage of reticulocytes in erythro				
arithmetic mean (standard deviation)	0.0030 (± 0.00235)	0.0017 (± 0.00258)	0.0007 (± 0.00350)	0.0020 (± 0.00283)

Notes:

[80] - Safety Population.

[81] - Safety Population.

[82] - Safety Population.

[83] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, high density lipoprotein (HDL) Cholesterol, low density lipoprotein (LDL) Cholesterol

End point title	Part 1: Change From Baseline in Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, high density lipoprotein (HDL) Cholesterol, low density lipoprotein (LDL) Cholesterol[84]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: glucose, cholesterol, triglycerides, calcium, chloride, phosphate, potassium, magnesium, sodium, urea, HDL cholesterol and LDL cholesterol. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. 99999 indicates data is not available. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[85]	6[86]	2[87]	
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Glucose, n=6,6,2	-0.20 (± 0.253)	0.28 (± 0.595)	0.00 (± 0.424)	
Cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Triglycerides, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Calcium, n=6,6,2	-0.007 (± 0.1343)	-0.027 (± 0.0468)	0.020 (± 0.0283)	
Chloride, n=6,6,2	0.0 (± 2.10)	0.8 (± 3.06)	-0.5 (± 3.54)	
Phosphate, n=6,6,2	0.042 (± 0.1594)	0.058 (± 0.1772)	-0.075 (± 0.1061)	
Potassium, n=6,6,2	0.02 (± 0.240)	-0.03 (± 0.242)	-0.10 (± 0.000)	

Magnesium, n=6,6,2	0.000 (± 0.0551)	-0.007 (± 0.0561)	-0.020 (± 0.0283)	
Sodium, n=6,6,2	0.2 (± 2.40)	-0.8 (± 1.60)	-1.0 (± 1.41)	
Urea, n=6,6,2	-0.08 (± 1.021)	-0.08 (± 0.801)	1.00 (± 0.000)	
HDL cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
LDL cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	

Notes:

[85] - Safety Population.

[86] - Safety Population.

[87] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Chemistry Parameters: Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST)

End point title	Part 1: Change From Baseline in Chemistry Parameters: Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST)[88]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: ALT, ALP and AST. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[89]	6[90]	2[91]	
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT	2.7 (± 7.79)	-1.7 (± 4.46)	9.5 (± 6.36)	
ALP	10.5 (± 23.36)	-3.5 (± 4.64)	-4.0 (± 1.41)	
AST	-0.5 (± 3.94)	-2.0 (± 8.60)	4.5 (± 2.12)	

Notes:

[89] - Safety Population.

[90] - Safety Population.

[91] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Chemistry Parameters: Creatinine, Bilirubin

End point title	Part 1: Change From Baseline in Chemistry Parameters: Creatinine, Bilirubin[92]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: creatinine and bilirubin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[93]	6[94]	2[95]	
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Creatinine	1.77 (± 5.565)	-1.33 (± 4.291)	0.00 (± 0.000)	
Bilirubin	-0.3 (± 3.20)	-2.0 (± 2.53)	3.0 (± 9.90)	

Notes:

[93] - Safety Population.

[94] - Safety Population.

[95] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Chemistry Parameters: Protein

End point title	Part 1: Change From Baseline in Chemistry Parameters:

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameter: protein. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[97]	6[98]	2[99]	
Units: Grams per liter				
arithmetic mean (standard deviation)	-1.3 (± 4.93)	-1.0 (± 2.97)	1.0 (± 2.83)	

Notes:

[97] - Safety Population.

[98] - Safety Population.

[99] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Chemistry Parameters: Amylase, Lipase

End point title	Part 1: Change From Baseline in Chemistry Parameters: Amylase, Lipase[100]

End point description:

Blood samples were collected to analyze the chemistry parameters: amylase and lipase. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed. Amylase and lipase results were collected for two participants in GSK3640254 10 mg arm during Part 1 of the study. No data were collected for Placebo and GSK3640254 200 mg arms at Visit 6 (Day 11) due to delays in approval of Protocol Amendment 02 into which testing for amylase and lipase was added.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 6 (Day 11)

Notes:

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2[101]	0[102]	0[103]	
Units: Units per liter				
arithmetic mean (standard deviation)				
Amylase	0.0 (± 11.31)	()	()	
Lipase	-2.0 (± 2.83)	()	()	

Notes:

[101] - Safety Population.

[102] - Safety Population.

[103] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Chemistry Parameters: Glucose,

Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol

End point title	Part 2: Change From Baseline in Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol[104]

End point description:

Blood samples were collected to analyze the chemistry parameters: glucose, cholesterol, triglycerides, calcium, chloride, phosphate, potassium, magnesium, sodium, urea, HDL cholesterol and LDL cholesterol. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant. 88888 indicates, data is not available.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[104] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[105]	6[106]	6[107]	1[108]
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Glucose, n=6,6,6,1	-0.05 (± 0.327)	0.18 (± 1.085)	-0.03 (± 0.446)	0.50 (± 99999)
Cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
Triglycerides, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
Calcium, n=6,6,6,1	-0.057 (± 0.0638)	-0.027 (± 0.0628)	0.030 (± 0.1002)	0.000 (± 99999)
Chloride, n=6,6,6,1	-0.7 (± 2.25)	-0.2 (± 1.47)	-0.7 (± 2.34)	-2.0 (± 99999)
Phosphate, n=6,6,6,1	-0.117 (± 0.2160)	0.067 (± 0.1211)	0.083 (± 0.1329)	0.000 (± 99999)
Potassium, n=6,6,6,1	-0.20 (± 0.261)	0.05 (± 0.383)	0.20 (± 0.210)	-0.10 (± 99999)
Magnesium, n=6,6,6,1	0.007 (± 0.0484)	0.007 (± 0.0413)	0.027 (± 0.0501)	0.000 (± 99999)
Sodium, n=6,6,6,1	-0.8 (± 2.23)	-0.3 (± 1.37)	-0.2 (± 1.72)	-4.0 (± 99999)
Urea, n=6,6,6,1	-0.42 (± 0.861)	-0.25 (± 1.037)	-0.33 (± 0.931)	-0.50 (± 99999)
HDL cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
LDL cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

Notes:

[105] - Safety Population.

[106] - Safety Population.

[107] - Safety Population.

[108] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Chemistry Parameters: ALT, ALP, AST

End point title	Part 2: Change From Baseline in Chemistry Parameters: ALT, ALP, AST[109]

End point description:

Blood samples were collected to analyze the chemistry parameters: ALT, ALP and AST. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed. 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[109] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[110]	6[111]	6[112]	1[113]
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT	-3.8 (± 6.62)	-1.2 (± 3.76)	-6.2 (± 8.33)	-1.0 (± 99999)
ALP	-3.2 (± 3.19)	-0.7 (± 5.35)	-1.8 (± 8.61)	-1.0 (± 99999)
AST	-5.2 (± 9.37)	0.3 (± 5.79)	-4.7 (± 7.37)	4.0 (± 99999)

Notes:

[110] - Safety Population.

[111] - Safety Population.

[112] - Safety Population.

[113] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Chemistry Parameters: Creatinine, Bilirubin

End point title	Part 2: Change From Baseline in Chemistry Parameters: Creatinine, Bilirubin[114]

End point description:

Blood samples were collected to analyze the chemistry parameters: creatinine and bilirubin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed. 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[114] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[115]	6[116]	6[117]	1[118]
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Creatinine	1.35 (± 3.230)	-3.38 (± 2.230)	-0.17 (± 8.362)	-0.90 (± 99999)
Bilirubin	-0.3 (± 2.34)	1.3 (± 6.02)	0.3 (± 1.51)	0.0 (± 99999)

Notes:

[115] - Safety Population.

[116] - Safety Population.

[117] - Safety Population.

[118] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Chemistry Parameters: Protein

End point title	Part 2: Change From Baseline in Chemistry Parameters:

End point description:

Blood samples were collected to analyze the chemistry parameter: protein. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed. 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[119] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[120]	6[121]	6[122]	1[123]
Units: Grams per liter				
arithmetic mean (standard deviation)	-2.2 (± 3.25)	-0.8 (± 4.07)	1.5 (± 4.64)	-2.0 (± 99999)

Notes:

[120] - Safety Population.

[121] - Safety Population.

[122] - Safety Population.

[123] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Chemistry Parameters: Amylase, Lipase

End point title	Part 2: Change From Baseline in Chemistry Parameters: Amylase, Lipase[124]

End point description:

Blood samples were collected to analyze the chemistry parameters: amylase and lipase. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the specified time points were analyzed. 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[125]	6[126]	6[127]	1[128]
Units: Units per liter				
arithmetic mean (standard deviation)				
Amylase	-2.3 (± 8.62)	0.8 (± 9.87)	6.7 (± 7.84)	-10.0 (± 99999)
Lipase	-1.0 (± 8.27)	-2.2 (± 6.37)	4.5 (± 8.29)	8.0 (± 99999)

Notes:

[125] - Safety Population.

[126] - Safety Population.

[127] - Safety Population.

[128] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Urinalysis Parameter: Specific Gravity

End point title	Part 1: Change From Baseline in Urinalysis Parameter: Specific Gravity[129]

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. Baseline was defined as the

latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[129] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[130]	6[131]	2[132]	
Units: Ratio				
arithmetic mean (standard deviation)	0.0002 (± 0.00615)	0.0008 (± 0.00232)	0.0000 (± 0.00283)	

Notes:

[130] - Safety Population.

[131] - Safety Population.

[132] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Urinalysis Parameter: Urobilinogen

End point title	Part 1: Change From Baseline in Urinalysis Parameter: Urobilinogen[133]

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: urobilinogen. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[133] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[134]	6[135]	2[136]	
Units: Micromoles per liter				
arithmetic mean (standard deviation)	4.50 (± 6.971)	0.00 (± 0.000)	0.00 (± 0.000)	

Notes:

[134] - Safety Population.

[135] - Safety Population.

[136] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Urinalysis Parameter: Potential of Hydrogen (pH)

End point title	Part 1: Change From Baseline in Urinalysis Parameter: Potential of Hydrogen (pH)[137]

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: pH. Urine pH is an acid-base measurement. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acidic pH (5.0 - 6.0). Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[137] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[138]	6[139]	2[140]	
Units: pH				
arithmetic mean (standard deviation)	0.17 (± 1.033)	-0.33 (± 0.683)	-0.50 (± 0.000)	

Notes:

[138] - Safety Population.

[139] - Safety Population.

[140] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Urinalysis Parameter: Specific Gravity

End point title	Part 2: Change From Baseline in Urinalysis Parameter: Specific Gravity[141]

End point description:

Urine samples were collected to analyze the urinalysis parameter: specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the

Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[142]	6[143]	6[144]	2[145]
Units: Ratio				
arithmetic mean (standard deviation)	0.0010 (± 0.00746)	-0.0022 (± 0.00794)	0.0018 (± 0.00744)	-0.0110 (± 0.00424)

Notes:

[142] - Safety Population.

[143] - Safety Population.

[144] - Safety Population.

[145] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Urinalysis Parameter: Urobilinogen

End point title	Part 2: Change From Baseline in Urinalysis Parameter: Urobilinogen[146]

End point description:

Urine samples were collected to analyze the urinalysis parameter: urobilinogen. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[146] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[147]	6[148]	6[149]	2[150]
Units: Micromoles per liter				
arithmetic mean (standard deviation)	0.00 (± 0.000)	4.50 (± 6.971)	0.00 (± 0.000)	0.00 (± 0.000)

Notes:

[147] - Safety Population.

[148] - Safety Population.

[149] - Safety Population.

[150] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Urinalysis Parameter: pH

End point title	Part 2: Change From Baseline in Urinalysis Parameter: pH[151]

End point description:

Urine samples were collected to analyze the urinalysis parameter: pH. Urine pH is an acid-base measurement. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acidic pH (5.0 - 6.0). Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[151] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[152]	6[153]	6[154]	2[155]
Units: pH				
arithmetic mean (standard deviation)	0.17 (± 0.683)	-0.17 (± 0.683)	0.08 (± 0.492)	0.25 (± 0.354)

Notes:

[152] - Safety Population.

[153] - Safety Population.

[154] - Safety Population.

[155] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Part 1: Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)[156]

End point description:

SBP and DBP were measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[156] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[157]	6[158]	2[159]	
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP	-2.5 (± 8.41)	0.5 (± 9.65)	-1.5 (± 3.54)	
DBP	-0.3 (± 14.50)	0.8 (± 4.67)	0.5 (± 0.71)	

Notes:

[157] - Safety Population.

[158] - Safety Population.

[159] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Respiratory Rate

End point title	Part 1: Change From Baseline in Respiratory Rate[160]

End point description:

Respiratory rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[160] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[161]	6[162]	2[163]	
Units: Breaths per minute				
arithmetic mean (standard deviation)	-1.0 (± 1.79)	0.2 (± 2.32)	-1.0 (± 1.41)	

Notes:

[161] - Safety Population.

[162] - Safety Population.

[163] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Pulse Rate

End point title	Part 1: Change From Baseline in Pulse Rate[164]

End point description:

Pulse rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[164] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[165]	6[166]	2[167]	
Units: Beats per minute				
arithmetic mean (standard deviation)	-5.2 (± 4.36)	5.5 (± 10.99)	6.0 (± 2.83)	

Notes:

[165] - Safety Population.

[166] - Safety Population.

[167] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in SBP and DBP

End point title	Part 2: Change From Baseline in SBP and DBP[168]

End point description:

SBP and DBP were measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[168] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[169]	6[170]	6[171]	2[172]
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP	1.0 (± 8.27)	-2.2 (± 4.45)	7.3 (± 11.55)	1.0 (± 2.83)
DBP	-1.8 (± 2.40)	-1.0 (± 6.36)	2.3 (± 15.72)	-0.5 (± 7.78)

Notes:

[169] - Safety Population.

[170] - Safety Population.

[171] - Safety Population.

[172] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Respiratory Rate

End point title	Part 2: Change From Baseline in Respiratory Rate[173]

End point description:

Respiratory rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[173] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[174]	6[175]	6[176]	2[177]
Units: Breaths per minute				
arithmetic mean (standard deviation)	-0.2 (± 1.83)	0.2 (± 1.47)	-1.0 (± 4.47)	0.5 (± 2.12)

Notes:

[174] - Safety Population.

[175] - Safety Population.

[176] - Safety Population.

[177] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in Pulse Rate

End point title	Part 2: Change From Baseline in Pulse Rate[178]

End point description:

Pulse rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[178] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[179]	6[180]	6[181]	2[182]
Units: Beats per minute				
arithmetic mean (standard deviation)	4.2 (± 17.36)	2.0 (± 11.14)	2.8 (± 6.40)	10.5 (± 7.78)

Notes:

[179] - Safety Population.

[180] - Safety Population.

[181] - Safety Population.

[182] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change From Baseline in Electrocardiogram (ECG) Parameters: PR Interval, QRS Duration, QT Interval, Corrected QT Interval Using Bazett's Formula (QTcB), Corrected QT Interval Using Fridericia's Formula (QTcF)

End point title	Part 1: Change From Baseline in Electrocardiogram (ECG) Parameters: PR Interval, QRS Duration, QT Interval, Corrected QT Interval Using Bazett's Formula (QTcB), Corrected QT Interval Using Fridericia's Formula (QTcF)[183]

End point description:

Twelve lead ECGs were obtained to measure PR Interval, QRS Duration, QT Interval, QTcB Interval and QTcF Interval. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Visit 5 (Days 8 to 10: Pre-dose, 2, 4 and 6 hours)

Notes:

[183] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[184]	6[185]	2[186]	
Units: Milliseconds				
arithmetic mean (standard deviation)				
PR Interval- Days 8 to 10: Pre-dose	-0.4 (± 5.32)	-7.6 (± 5.69)	-2.5 (± 2.12)	
PR Interval- Days 8 to 10: 2 hours	1.4 (± 5.47)	-6.3 (± 9.71)	-11.5 (± 0.71)	
PR Interval- Days 8 to 10: 4 hours	-0.1 (± 10.00)	0.2 (± 9.81)	-3.5 (± 0.71)	
PR Interval- Days 8 to 10: 6 hours	1.4 (± 13.22)	-5.9 (± 3.93)	-25.0 (± 4.24)	
QRS Duration- Days 8 to 10: Pre-dose	-3.1 (± 6.65)	-3.4 (± 9.90)	-5.3 (± 3.30)	
QRS Duration- Days 8 to 10: 2 hours	-2.1 (± 6.60)	0.4 (± 6.27)	0.2 (± 4.01)	
QRS Duration- Days 8 to 10: 4 hours	-3.3 (± 3.50)	-1.7 (± 6.75)	-1.3 (± 3.77)	
QRS Duration- Days 8 to 10: 6 hours	-3.6 (± 5.56)	-2.9 (± 4.55)	-2.3 (± 13.20)	
QT Interval- Days 8 to 10: Pre-dose	0.7 (± 8.15)	-2.7 (± 19.60)	-19.7 (± 21.21)	
QT Interval- Days 8 to 10: 2 hours	-2.4 (± 17.61)	4.4 (± 20.33)	-28.7 (± 4.24)	
QT Interval- Days 8 to 10: 4 hours	8.7 (± 18.43)	8.9 (± 13.72)	-25.2 (± 19.09)	
QT Interval- Days 8 to 10: 6 hours	5.7 (± 16.48)	5.8 (± 14.19)	-24.2 (± 21.92)	
QTcB Interval- Days 8 to 10: Pre-dose	1.65 (± 15.813)	3.60 (± 18.218)	-1.38 (± 6.435)	
QTcB Interval- Days 8 to 10: 2 hours	-10.45 (± 22.433)	-4.60 (± 14.266)	-27.38 (± 32.315)	
QTcB Interval- Days 8 to 10: 4 hours	0.77 (± 15.517)	-10.37 (± 20.176)	-30.23 (± 51.760)	
QTcB Interval- Days 8 to 10: 6 hours	2.65 (± 13.391)	-9.15 (± 15.513)	-4.88 (± 11.102)	
QTcF Interval- Days 8 to 10: Pre-dose	1.2 (± 10.75)	1.2 (± 9.56)	-7.7 (± 11.31)	
QTcF Interval- Days 8 to 10: 2 hours	-7.5 (± 19.44)	-1.3 (± 14.06)	-27.7 (± 22.63)	
QTcF Interval- Days 8 to 10: 4 hours	3.7 (± 15.18)	-3.7 (± 10.84)	-28.7 (± 41.01)	
QTcF Interval- Days 8 to 10: 6 hours	4.0 (± 12.82)	-3.8 (± 13.06)	-12.2 (± 14.85)	

Notes:

[184] - Safety Population.

[185] - Safety Population.

[186] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in ECG Parameters: PR Interval, QRS Duration, QT Interval, QTcB, QTcF

End point title	Part 2: Change From Baseline in ECG Parameters: PR Interval, QRS Duration, QT Interval, QTcB, QTcF[187]

End point description:

Twelve lead ECGs were obtained to measure PR Interval, QRS Duration, QT Interval, QTcB Interval and QTcF Interval. Baseline was defined as the latest pre-dose assessment with a non-missing value,

including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Visit 5 (Day 7: Pre-dose, 2, 4 and 6 hours)

Notes:

[187] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[188]	6[189]	6[190]	2[191]
Units: Milliseconds				
arithmetic mean (standard deviation)				
PR Interval- Day 7: Pre-dose	9.7 (± 13.92)	-1.1 (± 6.89)	-7.3 (± 9.20)	-7.3 (± 0.47)
PR Interval- Day 7: 2 hours	6.1 (± 14.20)	-2.4 (± 7.90)	-3.1 (± 8.61)	6.2 (± 2.59)
PR Interval- Day 7: 4 hours	5.2 (± 22.87)	1.1 (± 8.56)	-8.3 (± 6.81)	4.7 (± 5.19)
PR Interval- Day 7: 6 hours	3.9 (± 16.80)	-2.3 (± 6.24)	-2.1 (± 5.82)	-7.8 (± 9.66)
QRS Duration- Day 7: Pre-dose	3.9 (± 5.11)	3.2 (± 7.81)	-0.4 (± 6.87)	2.3 (± 7.07)
QRS Duration- Day 7: 2 hours	2.4 (± 4.18)	0.7 (± 4.89)	-0.1 (± 8.45)	4.3 (± 1.41)
QRS Duration- Day 7: 4 hours	1.7 (± 4.06)	0.1 (± 4.41)	-3.1 (± 6.25)	3.8 (± 3.54)
QRS Duration- Day 7: 6 hours	0.5 (± 11.78)	-0.1 (± 3.04)	-0.8 (± 3.70)	2.8 (± 6.36)
QT Interval- Day 7: Pre-dose	-7.4 (± 33.78)	-1.6 (± 13.03)	5.0 (± 20.49)	3.2 (± 2.59)
QT Interval- Day 7: 2 hours	-24.4 (± 33.17)	-4.4 (± 8.90)	1.8 (± 12.60)	-0.3 (± 6.13)
QT Interval- Day 7: 4 hours	-12.8 (± 25.96)	4.2 (± 12.84)	-1.7 (± 13.65)	11.2 (± 19.56)
QT Interval- Day 7: 6 hours	-21.4 (± 36.18)	5.9 (± 12.19)	0.7 (± 12.92)	2.7 (± 7.54)
QTcB Interval- Day 7: Pre-dose	-4.16 (± 14.780)	0.34 (± 11.468)	3.45 (± 6.785)	-7.08 (± 2.569)
QTcB Interval- Day 7: 2 hours	2.90 (± 19.936)	0.09 (± 14.494)	-4.88 (± 17.444)	-18.23 (± 2.923)
QTcB Interval- Day 7: 4 hours	-6.96 (± 23.150)	-0.56 (± 13.559)	1.30 (± 14.341)	-23.83 (± 2.781)
QTcB Interval- Day 7: 6 hours	-3.26 (± 16.691)	4.17 (± 12.302)	-1.68 (± 10.181)	-9.83 (± 17.489)
QTcF Interval- Day 7: Pre-dose	-5.9 (± 18.89)	-0.5 (± 4.12)	4.1 (± 9.23)	-3.3 (± 0.94)
QTcF Interval- Day 7: 2 hours	-7.2 (± 22.91)	-1.3 (± 8.73)	-2.3 (± 12.87)	-12.3 (± 0.47)
QTcF Interval- Day 7: 4 hours	-9.4 (± 21.24)	1.2 (± 8.15)	0.6 (± 9.00)	-12.3 (± 4.71)
QTcF Interval- Day 7: 6 hours	-9.5 (± 19.08)	4.5 (± 5.69)	-0.8 (± 7.79)	-5.8 (± 8.72)

Notes:

[188] - Safety Population.

[189] - Safety Population.

[190] - Safety Population.

[191] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count

End point title	Part 1: Absolute Values for Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count[192]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameters: basophils, eosinophils, lymphocytes, monocytes, neutrophils, leukocytes and platelet count. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[192] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[193]	6[194]	2[195]	
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Basophils, n=6,5,2	0.052 (± 0.0279)	0.056 (± 0.0321)	0.030 (± 0.0000)	
Days 8 to 10: Basophils, n=6,6,2	0.057 (± 0.0266)	0.037 (± 0.0186)	0.045 (± 0.0212)	
Baseline (Day 1): Eosinophils, n=6,5,2	0.212 (± 0.1783)	0.150 (± 0.0616)	0.105 (± 0.0212)	
Days 8 to 10: Eosinophils, n=6,6,2	0.188 (± 0.0873)	0.202 (± 0.1003)	0.080 (± 0.0424)	
Baseline (Day 1): Lymphocytes, n=6,5,2	2.303 (± 0.5431)	1.810 (± 0.4341)	2.010 (± 0.0707)	
Days 8 to 10: Lymphocytes, n=6,6,2	2.277 (± 0.4484)	2.217 (± 0.6693)	2.080 (± 0.1273)	
Baseline (Day 1): Monocytes, n=6,5,2	0.552 (± 0.2033)	0.530 (± 0.1814)	0.460 (± 0.0000)	
Days 8 to 10: Monocytes, n=6,6,2	0.652 (± 0.1907)	0.508 (± 0.2088)	0.515 (± 0.0212)	
Baseline (Day 1): Neutrophils, n=6,5,2	2.935 (± 0.4803)	3.094 (± 0.7279)	1.840 (± 0.4101)	
Days 8 to 10: Neutrophils, n=6,6,2	2.890 (± 0.6049)	2.635 (± 0.4068)	2.185 (± 0.2616)	
Baseline (Day 1): Leukocytes, n=6,5,2	6.05 (± 1.071)	5.64 (± 1.172)	4.45 (± 0.495)	
Days 8 to 10: Leukocytes, n=6,6,2	6.07 (± 0.929)	5.60 (± 1.158)	4.90 (± 0.283)	
Baseline (Day 1): Platelet count, n=6,5,2	208.8 (± 38.48)	202.0 (± 39.26)	195.5 (± 12.02)	
Days 8 to 10: Platelet count, n=6,6,2	233.8 (± 70.34)	205.0 (± 43.38)	208.5 (± 14.85)	

Notes:

[193] - Safety Population.

[194] - Safety Population.

[195] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Hemoglobin

End point title	Part 1: Absolute Values for Hematology Parameter: Hemoglobin[196]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[196] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[197]	6[198]	2[199]	
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	144.2 (± 11.55)	135.4 (± 9.42)	148.0 (± 4.24)	
Days 8 to 10: n=6,6,2	140.0 (± 12.18)	138.7 (± 12.72)	147.0 (± 9.90)	

Notes:

[197] - Safety Population.

[198] - Safety Population.

[199] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Hematocrit

End point title	Part 1: Absolute Values for Hematology Parameter:

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: hematocrit. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[200] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline

period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[201]	6[202]	2[203]	
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	0.4338 (± 0.02709)	0.4112 (± 0.02523)	0.4395 (± 0.01344)	
Days 8 to 10: n=6,6,2	0.4222 (± 0.03456)	0.4158 (± 0.02827)	0.4385 (± 0.03182)	

Notes:

[201] - Safety Population.

[202] - Safety Population.

[203] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Erythrocytes

End point title	Part 1: Absolute Values for Hematology Parameter: Erythrocytes[204]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[204] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[205]	6[206]	2[207]	
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	4.90 (± 0.228)	4.58 (± 0.259)	4.90 (± 0.283)	
Days 8 to 10: n=6,6,2	4.80 (± 0.290)	4.63 (± 0.327)	4.90 (± 0.424)	

Notes:

[205] - Safety Population.

[206] - Safety Population.

[207] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Volume

End point title	Part 1: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Volume[208]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes mean corpuscular volume. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[208] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[209]	6[210]	2[211]	
Units: Femtoliter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	88.5 (± 3.67)	90.2 (± 3.49)	90.0 (± 1.41)	
Days 8 to 10: n=6,6,2	88.5 (± 4.09)	90.0 (± 2.28)	90.0 (± 1.41)	

Notes:

[209] - Safety Population.

[210] - Safety Population.

[211] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin

End point title	Part 1: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin[212]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: erythrocytes mean corpuscular hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[212] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[213]	6[214]	2[215]	
Units: Picograms				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	29.38 (± 1.780)	29.64 (± 0.879)	30.25 (± 0.636)	
Days 8 to 10: n=6,6,2	29.30 (± 1.747)	29.97 (± 0.942)	30.10 (± 0.707)	

Notes:

[213] - Safety Population.

[214] - Safety Population.

[215] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Hematology Parameter: Reticulocytes/Erythro

End point title	Part 1: Absolute Values for Hematology Parameter: Reticulocytes/Erythro[216]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the hematology parameter: reticulocytes/erythro. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[216] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[217]	6[218]	2[219]	
Units: Percentage of reticulocytes in erythro				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,5,2	0.0137 (± 0.00726)	0.0078 (± 0.00349)	0.0110 (± 0.00424)	
Days 8 to 10: n=6,6,2	0.0178 (± 0.01139)	0.0088 (± 0.00264)	0.0130 (± 0.00424)	

Notes:

[217] - Safety Population.

[218] - Safety Population.

[219] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count

End point title	Part 2: Absolute Values for Hematology Parameters: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Leukocytes, Platelet Count[220]

End point description:

Blood samples were collected to analyze the hematology parameters: basophils, eosinophils, lymphocytes, monocytes, neutrophils, leukocytes and platelet count. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[220] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[221]	6[222]	6[223]	2[224]
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Basophils, n=6,6,5,2	0.042 (± 0.0232)	0.042 (± 0.0117)	0.030 (± 0.0200)	0.040 (± 0.0283)
Day 7: Basophils, n=5,6,5,2	0.050 (± 0.0274)	0.062 (± 0.0223)	0.054 (± 0.0251)	0.035 (± 0.0071)
Baseline (Day 1): Eosinophils, n=6,6,5,2	0.402 (± 0.3307)	0.290 (± 0.2628)	0.320 (± 0.2542)	0.055 (± 0.0354)
Day 7: Eosinophils, n=5,6,5,2	0.316 (± 0.1780)	0.243 (± 0.1546)	0.210 (± 0.1239)	0.075 (± 0.0354)
Baseline (Day 1): Lymphocytes, n=6,6,5,2	1.990 (± 0.3013)	2.047 (± 0.6167)	2.236 (± 0.3010)	1.865 (± 0.3606)
Day 7: Lymphocytes, n=5,6,5,2	1.960 (± 0.3450)	1.985 (± 0.2983)	2.694 (± 0.7060)	1.755 (± 0.0919)
Baseline (Day 1): Monocytes, n=6,6,5,2	0.560 (± 0.2082)	0.477 (± 0.1442)	0.534 (± 0.1459)	0.435 (± 0.1061)
Day 7: Monocytes, n=5,6,5,2	0.530 (± 0.2210)	0.498 (± 0.2647)	0.414 (± 0.1467)	0.305 (± 0.0071)
Baseline (Day 1): Neutrophils, n=6,6,5,2	2.512 (± 1.2631)	2.442 (± 1.1951)	3.060 (± 0.5711)	2.280 (± 1.0465)
Day 7: Neutrophils, n=5,6,5,2	2.826 (± 1.1821)	4.120 (± 2.9025)	3.344 (± 0.6322)	2.065 (± 1.3647)

Baseline (Day 1): Leukocytes, n=6,6,5,2	5.50 (± 1.633)	5.28 (± 1.947)	6.20 (± 0.938)	4.65 (± 1.485)
Day 7: Leukocytes, n=5,6,6,2	5.66 (± 1.527)	6.90 (± 3.310)	6.55 (± 0.973)	4.20 (± 1.414)
Baseline (Day 1): Platelet count, n=5,6,5,2	276.6 (± 54.29)	236.7 (± 41.87)	232.2 (± 40.12)	197.0 (± 59.40)
Day 7: Platelet count, n=4,6,6,2	292.0 (± 77.06)	254.2 (± 37.39)	249.0 (± 38.72)	201.5 (± 60.10)

Notes:

[221] - Safety Population.

[222] - Safety Population.

[223] - Safety Population.

[224] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Hemoglobin

End point title	Part 2: Absolute Values for Hematology Parameter: Hemoglobin[225]

End point description:

Blood samples were collected to analyze the hematology parameter: hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[225] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[226]	6[227]	6[228]	2[229]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	136.3 (± 16.34)	149.2 (± 13.44)	141.2 (± 7.98)	147.0 (± 7.07)
Day 7: n=5,6,6,2	129.4 (± 19.55)	144.5 (± 7.87)	135.8 (± 11.02)	139.0 (± 8.49)

Notes:

[226] - Safety Population.

[227] - Safety Population.

[228] - Safety Population.

[229] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Hematocrit

End point title	Part 2: Absolute Values for Hematology Parameter:

End point description:

Blood samples were collected to analyze the hematology parameter: hematocrit. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[230] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[231]	6[232]	6[233]	2[234]
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	0.4037 (± 0.04646)	0.4505 (± 0.02992)	0.4222 (± 0.01879)	0.4330 (± 0.01838)
Day 7: n=5,6,6,2	0.3826 (± 0.05125)	0.4382 (± 0.01579)	0.4062 (± 0.03107)	0.4015 (± 0.03323)

Notes:

[231] - Safety Population.

[232] - Safety Population.

[233] - Safety Population.

[234] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Erythrocytes

End point title	Part 2: Absolute Values for Hematology Parameter: Erythrocytes[235]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[235] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[236]	6[237]	6[238]	2[239]
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	4.53 (± 0.476)	5.17 (± 0.450)	4.74 (± 0.230)	4.80 (± 0.000)
Day 7: n=5,6,6,2	4.26 (± 0.503)	5.00 (± 0.518)	4.52 (± 0.431)	4.50 (± 0.000)

Notes:

[236] - Safety Population.

[237] - Safety Population.

[238] - Safety Population.

[239] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Volume

End point title	Part 2: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Volume[240]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes mean corpuscular volume. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[240] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[241]	6[242]	6[243]	2[244]
Units: Femtoliter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	88.8 (± 3.76)	87.8 (± 8.59)	89.2 (± 1.64)	91.0 (± 4.24)
Day 7: n=5,6,6,2	89.6 (± 3.44)	88.0 (± 8.53)	90.0 (± 2.97)	89.0 (± 7.07)

Notes:

[241] - Safety Population.

[242] - Safety Population.

[243] - Safety Population.

[244] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin

End point title	Part 2: Absolute Values for Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin[245]

End point description:

Blood samples were collected to analyze the hematology parameter: erythrocytes mean corpuscular hemoglobin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[245] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[246]	6[247]	6[248]	2[249]
Units: Picograms				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	30.07 (± 1.870)	29.15 (± 3.531)	29.80 (± 0.925)	30.95 (± 1.485)
Day 7: n=5,6,6,2	30.22 (± 2.017)	29.10 (± 3.553)	29.97 (± 0.898)	30.90 (± 1.838)

Notes:

[246] - Safety Population.

[247] - Safety Population.

[248] - Safety Population.

[249] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Hematology Parameter: Reticulocytes/Erythro

End point title	Part 2: Absolute Values for Hematology Parameter: Reticulocytes/Erythro[250]

End point description:

Blood samples were collected to analyze the hematology parameter: reticulocytes/erythro. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[250] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[251]	6[252]	6[253]	2[254]
Units: Percentage of reticulocytes in erythro				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,5,2	0.0102 (± 0.00223)	0.0082 (± 0.00147)	0.0108 (± 0.00492)	0.0070 (± 0.00141)
Day 7: n=5,6,6,2	0.0124 (± 0.00297)	0.0098 (± 0.00160)	0.0107 (± 0.00344)	0.0090 (± 0.00141)

Notes:

[251] - Safety Population.

[252] - Safety Population.

[253] - Safety Population.

[254] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol

End point title	Part 1: Absolute Values for Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol[255]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: glucose, cholesterol, triglycerides, calcium, chloride, phosphate, potassium, magnesium, sodium, urea, HDL cholesterol and LDL cholesterol. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates data is not available.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[255] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[256]	6[257]	2[258]	
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Glucose, n=6,6,2	5.28 (± 0.556)	4.88 (± 0.546)	5.40 (± 0.141)	
Days 8 to 10: Glucose, n=6,6,2	5.08 (± 0.618)	5.17 (± 0.528)	5.40 (± 0.283)	
Baseline (Day 1): Cholesterol, n=6,6,2	4.700 (± 1.2345)	4.058 (± 0.9641)	4.350 (± 0.6364)	
Days 8 to 10: Cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Baseline (Day 1): Triglycerides, n=6,6,2	1.070 (± 0.4527)	1.150 (± 0.5114)	0.950 (± 0.4101)	
Days 8 to 10: Triglycerides, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Baseline (Day 1): Calcium, n=6,6,2	2.300 (± 0.1073)	2.313 (± 0.0961)	2.330 (± 0.0141)	
Days 8 to 10: Calcium, n=6,6,2	2.293 (± 0.0816)	2.287 (± 0.0561)	2.350 (± 0.0424)	
Baseline (Day 1): Chloride, n=6,6,2	104.2 (± 0.41)	105.8 (± 2.48)	105.0 (± 2.83)	
Days 8 to 10: Chloride, n=6,6,2	104.2 (± 1.72)	106.7 (± 1.21)	104.5 (± 0.71)	
Baseline (Day 1): Phosphate, n=6,6,2	1.117 (± 0.1835)	1.083 (± 0.1889)	1.200 (± 0.0707)	
Days 8 to 10: Phosphate, n=6,6,2	1.158 (± 0.1882)	1.142 (± 0.2245)	1.125 (± 0.1768)	
Baseline (Day 1): Potassium, n=6,6,2	4.10 (± 0.210)	4.30 (± 0.276)	4.15 (± 0.212)	
Days 8 to 10: Potassium, n=6,6,2	4.12 (± 0.349)	4.27 (± 0.216)	4.05 (± 0.212)	
Baseline (Day 1): Magnesium, n=6,6,2	0.847 (± 0.0393)	0.853 (± 0.0450)	0.880 (± 0.0283)	
Days 8 to 10: Magnesium, n=6,6,2	0.847 (± 0.0561)	0.847 (± 0.0393)	0.860 (± 0.0000)	
Baseline (Day 1): Sodium, n=6,6,2	138.3 (± 2.25)	139.8 (± 0.75)	139.0 (± 0.00)	
Days 8 to 10: Sodium, n=6,6,2	138.5 (± 2.17)	139.0 (± 0.89)	138.0 (± 1.41)	
Baseline (Day 1): Urea, n=6,6,2	5.33 (± 0.516)	5.83 (± 1.169)	5.00 (± 0.707)	
Days 8 to 10: Urea, n=6,6,2	5.25 (± 1.037)	5.75 (± 0.524)	6.00 (± 0.707)	
Baseline (Day 1): HDL cholesterol, n=6,6,2	1.192 (± 0.1960)	1.025 (± 0.0612)	1.075 (± 0.0354)	
Days 8 to 10: HDL cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Baseline (Day 1): LDL cholesterol, n=6,6,2	3.017 (± 1.0452)	2.507 (± 0.7842)	2.840 (± 0.4808)	
Days 8 to 10: LDL cholesterol, n=0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	

Notes:

[256] - Safety Population.

[257] - Safety Population.

[258] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Chemistry Parameters: ALT, ALP, AST

End point title	Part 1: Absolute Values for Chemistry Parameters: ALT, ALP, AST[259]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: ALT, ALP and AST. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[259] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[260]	6[261]	2[262]	
Units: International units per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): ALT	31.3 (± 15.67)	19.7 (± 15.82)	20.0 (± 8.49)	
Days 8 to 10: ALT	34.0 (± 21.58)	18.0 (± 11.85)	29.5 (± 14.85)	
Baseline (Day 1): ALP	62.0 (± 10.55)	62.3 (± 19.13)	63.0 (± 2.83)	
Days 8 to 10: ALP	72.5 (± 27.68)	58.8 (± 16.46)	59.0 (± 1.41)	
Baseline (Day 1): AST	26.7 (± 9.42)	23.3 (± 10.76)	20.0 (± 8.49)	
Days 8 to 10: AST	26.2 (± 11.27)	21.3 (± 4.63)	24.5 (± 10.61)	

Notes:

[260] - Safety Population.

[261] - Safety Population.

[262] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Chemistry Parameters: Creatinine, Bilirubin

End point title	Part 1: Absolute Values for Chemistry Parameters: Creatinine, Bilirubin[263]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameters: creatinine and bilirubin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[263] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[264]	6[265]	2[266]	
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Creatinine	82.05 (± 11.319)	81.35 (± 3.861)	88.40 (± 3.818)	
Days 8 to 10: Creatinine	83.82 (± 13.674)	80.02 (± 6.239)	88.40 (± 3.818)	
Baseline (Day 1): Bilirubin	11.7 (± 6.38)	8.0 (± 2.83)	15.0 (± 1.41)	
Days 8 to 10: Bilirubin	11.3 (± 3.50)	6.0 (± 1.79)	18.0 (± 8.49)	

Notes:

[264] - Safety Population.

[265] - Safety Population.

[266] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Chemistry Parameters: Protein

End point title	Part 1: Absolute Values for Chemistry Parameters: Protein[267]

End point description:

Blood samples were collected at Baseline and one sample between Days 8 to 10 to analyze the chemistry parameter: protein. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[267] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[268]	6[269]	2[270]	
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1)	72.2 (± 3.06)	70.3 (± 2.34)	69.0 (± 1.41)	
Days 8 to 10	70.8 (± 3.60)	69.3 (± 5.05)	70.0 (± 1.41)	

Notes:

[268] - Safety Population.

[269] - Safety Population.

[270] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Chemistry Parameters: Amylase, Lipase

End point title	Part 1: Absolute Values for Chemistry Parameters: Amylase, Lipase[271]

End point description:

Blood samples were collected to analyze the chemistry parameters: amylase and lipase. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed. Amylase and lipase results were collected for two participants in GSK3640254 10 mg arm during Part 1 of the study. No data were collected for Placebo and GSK3640254 200 mg arms at Visit 6 (Day 11) due to delays in approval of Protocol Amendment 02 into which testing for amylase and lipase was added.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 6 (Day 11)

Notes:

[271] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2[272]	0[273]	0[274]	
Units: Units per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Amylase	57.0 (± 11.31)	()	()	
Day 11: Amylase	57.0 (± 0.00)	()	()	
Baseline (Day 1): Lipase	28.5 (± 4.95)	()	()	
Day 11: Lipase	26.5 (± 7.78)	()	()	

Notes:

[272] - Safety Population.

[273] - Safety Population.

[274] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol

End point title	Part 2: Absolute Values for Chemistry Parameters: Glucose, Cholesterol, Triglycerides, Calcium, Chloride, Phosphate, Potassium, Magnesium, Sodium, Urea, HDL Cholesterol, LDL Cholesterol[275]

End point description:

Blood samples were collected to analyze the chemistry parameters: glucose, cholesterol, triglycerides, calcium, chloride, phosphate, potassium, magnesium, sodium, urea, HDL cholesterol and LDL cholesterol. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant. 88888 indicates data is not available.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[275] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[276]	6[277]	6[278]	2[279]
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Glucose, n=6,6,6,2	4.68 (± 0.306)	4.72 (± 0.928)	4.80 (± 0.456)	4.90 (± 0.849)
Day 7: Glucose, n=6,6,6,1	4.63 (± 0.408)	4.90 (± 0.190)	4.77 (± 0.320)	4.80 (± 99999)
Baseline (Day 1): Cholesterol, n=6,6,6,2	4.233 (± 0.6758)	4.375 (± 1.1626)	4.150 (± 0.8573)	3.400 (± 0.3536)
Day 7: Cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
Baseline (Day 1): Triglycerides, n=6,6,6,2	1.183 (± 0.1924)	1.447 (± 0.6008)	1.120 (± 0.4879)	0.540 (± 0.1980)
Day 7: Triglycerides, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
Baseline (Day 1): Calcium, n=6,6,6,2	2.330 (± 0.0629)	2.320 (± 0.0980)	2.290 (± 0.0701)	2.280 (± 0.0849)
Day 7: Calcium, n=6,6,6,1	2.273 (± 0.0628)	2.293 (± 0.0766)	2.320 (± 0.0780)	2.220 (± 99999)
Baseline (Day 1): Chloride, n=6,6,6,2	103.0 (± 1.67)	102.2 (± 2.64)	103.7 (± 2.34)	105.5 (± 0.71)
Day 7: Chloride, n=6,6,6,1	102.3 (± 1.51)	102.0 (± 1.79)	103.0 (± 1.10)	104.0 (± 99999)
Baseline (Day 1): Phosphate, n=6,6,6,2	1.317 (± 0.1693)	1.108 (± 0.1281)	1.083 (± 0.1211)	0.950 (± 0.2828)
Day 7: Phosphate, n=6,6,6,1	1.200 (± 0.1265)	1.175 (± 0.1969)	1.167 (± 0.1329)	0.750 (± 99999)
Baseline (Day 1): Potassium, n=6,6,6,2	4.07 (± 0.476)	3.98 (± 0.325)	3.95 (± 0.164)	4.10 (± 0.424)
Day 7: Potassium, n=6,6,6,1	3.87 (± 0.273)	4.03 (± 0.242)	4.15 (± 0.122)	3.70 (± 99999)
Baseline (Day 1): Magnesium, n=6,6,6,2	0.790 (± 0.0395)	0.830 (± 0.0518)	0.803 (± 0.0320)	0.810 (± 0.0707)
Day 7: Magnesium, n=6,6,6,1	0.797 (± 0.0731)	0.837 (± 0.0427)	0.830 (± 0.0654)	0.760 (± 99999)
Baseline (Day 1): Sodium, n=6,6,6,2	137.7 (± 1.63)	138.5 (± 2.43)	137.8 (± 3.06)	140.5 (± 2.12)
Day 7: Sodium, n=6,6,6,1	136.8 (± 3.54)	138.2 (± 1.94)	137.7 (± 1.97)	138.0 (± 99999)
Baseline (Day 1): Urea, n=6,6,6,2	4.50 (± 1.517)	4.25 (± 1.508)	5.92 (± 1.068)	6.25 (± 2.475)
Day 7: Urea, n=6,6,6,1	4.08 (± 0.970)	4.00 (± 0.632)	5.58 (± 0.492)	4.00 (± 99999)
Baseline (Day 1): HDL cholesterol, n=6,6,6,2	1.242 (± 0.3277)	1.133 (± 0.3312)	1.200 (± 0.3194)	1.250 (± 0.0707)
Day 7: HDL cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
Baseline (Day 1): LDL cholesterol, n=6,6,6,2	2.448 (± 0.6649)	2.578 (± 0.8267)	2.437 (± 0.6955)	1.905 (± 0.3748)
Day 7: LDL cholesterol, n=0,0,0,0	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

Notes:

[276] - Safety Population.

[277] - Safety Population.

[278] - Safety Population.

[279] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Chemistry Parameters: ALT, ALP, AST

End point title	Part 2: Absolute Values for Chemistry Parameters: ALT, ALP, AST[280]

End point description:

Blood samples were collected to analyze the chemistry parameters: ALT, ALP and AST. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[280] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[281]	6[282]	6[283]	2[284]
Units: International units per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): ALT, n=6,6,6,2	18.3 (± 14.07)	17.8 (± 7.63)	33.2 (± 23.07)	34.5 (± 6.36)
Day 7: ALT, n=6,6,6,1	14.5 (± 7.66)	16.7 (± 5.24)	27.0 (± 18.00)	29.0 (± 99999)
Baseline (Day 1): ALP, n=6,6,6,2	63.3 (± 15.08)	63.7 (± 4.68)	60.8 (± 9.00)	43.0 (± 18.38)
Day 7: ALP, n=6,6,6,1	60.2 (± 16.53)	63.0 (± 5.25)	59.0 (± 5.18)	55.0 (± 99999)
Baseline (Day 1): AST, n=6,6,6,2	26.8 (± 15.39)	18.5 (± 6.60)	26.7 (± 8.14)	50.0 (± 39.60)
Day 7: AST, n=6,6,6,1	21.7 (± 6.74)	18.8 (± 3.31)	22.0 (± 3.74)	26.0 (± 99999)

Notes:

[281] - Safety Population.

[282] - Safety Population.

[283] - Safety Population.

[284] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Chemistry Parameters: Creatinine, Bilirubin

End point title	Part 2: Absolute Values for Chemistry Parameters: Creatinine, Bilirubin[285]

End point description:

Blood samples were collected to analyze the chemistry parameters: creatinine and bilirubin. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[285] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[286]	6[287]	6[288]	2[289]
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Creatinine, n=6,6,6,2	71.30 (± 12.207)	73.67 (± 7.120)	73.52 (± 12.761)	86.65 (± 13.789)
Day 7: Creatinine, n=6,6,6,1	72.65 (± 14.109)	70.28 (± 8.269)	73.35 (± 8.195)	76.00 (± 99999)
Baseline (Day 1): Bilirubin, n=6,6,6,2	10.0 (± 5.66)	9.3 (± 1.03)	7.7 (± 3.44)	11.0 (± 7.07)
Day 7: Bilirubin, n=6,6,6,1	9.7 (± 4.97)	10.7 (± 5.47)	8.0 (± 2.83)	6.0 (± 99999)

Notes:

[286] - Safety Population.

[287] - Safety Population.

[288] - Safety Population.

[289] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Chemistry Parameters: Protein

End point title	Part 2: Absolute Values for Chemistry Parameters: Protein[290]

End point description:

Blood samples were collected to analyze the chemistry parameter: protein. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[290] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[291]	6[292]	6[293]	2[294]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): n=6,6,6,2	78.8 (± 12.78)	73.3 (± 5.50)	76.7 (± 10.03)	73.5 (± 0.71)
Day 7: n=6,6,6,1	76.7 (± 12.01)	72.5 (± 5.13)	78.2 (± 8.93)	72.0 (± 99999)

Notes:

[291] - Safety Population.

[292] - Safety Population.

[293] - Safety Population.

[294] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Chemistry Parameters: Amylase, Lipase

End point title	Part 2: Absolute Values for Chemistry Parameters: Amylase, Lipase[295]

End point description:

Blood samples were collected to analyze the chemistry parameters: amylase and lipase. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles). 99999 indicates that, standard deviation could not be calculated for single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[295] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[296]	6[297]	6[298]	2[299]
Units: Units per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1): Amylase, n=6,6,6,2	47.2 (± 18.15)	51.0 (± 21.65)	55.2 (± 18.61)	56.0 (± 25.46)
Day 7: Amylase, n=6,6,6,1	44.8 (± 17.81)	51.8 (± 22.71)	61.8 (± 25.86)	64.0 (± 99999)
Baseline (Day 1): Lipase, n=6,6,6,2	26.5 (± 14.08)	29.7 (± 10.95)	43.2 (± 32.32)	26.0 (± 14.14)
Day 7: Lipase, n=6,6,6,1	25.5 (± 11.64)	27.5 (± 13.40)	47.7 (± 34.70)	44.0 (± 99999)

Notes:

[296] - Safety Population.

[297] - Safety Population.

[298] - Safety Population.

[299] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Urinalysis Parameter: Specific Gravity

End point title	Part 1: Absolute Values for Urinalysis Parameter: Specific Gravity[300]

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[300] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[301]	6[302]	2[303]	
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline (Day 1)	1.0238 (± 0.00677)	1.0233 (± 0.00320)	1.0240 (± 0.00283)	
Days 8 to 10	1.0240 (± 0.00533)	1.0242 (± 0.00279)	1.0240 (± 0.00000)	

Notes:

[301] - Safety Population.

[302] - Safety Population.

[303] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Urinalysis Parameter: Urobilinogen

End point title	Part 1: Absolute Values for Urinalysis Parameter:

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: urobilinogen. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[304] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[305]	6[306]	2[307]	
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1)	3.40 (± 0.000)	3.40 (± 0.000)	3.40 (± 0.000)	
Days 8 to 10	7.90 (± 6.971)	3.40 (± 0.000)	3.40 (± 0.000)	

Notes:

[305] - Safety Population.

[306] - Safety Population.

[307] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Urinalysis Parameter: pH

End point title	Part 1: Absolute Values for Urinalysis Parameter: pH[308]

End point description:

Urine samples were collected at Baseline and one sample between Days 8 to 10 to analyze the urinalysis parameter: pH. Urine pH is an acid-base measurement. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acidic pH (5.0 - 6.0). Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[308] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[309]	6[310]	2[311]	
Units: pH				
arithmetic mean (standard deviation)				
Baseline (Day 1)	5.67 (± 0.931)	5.75 (± 0.689)	5.75 (± 0.354)	
Days 8 to 10	5.83 (± 0.753)	5.42 (± 0.585)	5.25 (± 0.354)	

Notes:

[309] - Safety Population.

[310] - Safety Population.

[311] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Urinalysis Parameter: Specific Gravity

End point title	Part 2: Absolute Values for Urinalysis Parameter: Specific Gravity[312]

End point description:

Urine samples were collected to analyze the urinalysis parameter: specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[312] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[313]	6[314]	6[315]	2[316]
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline (Day 1)	1.0223 (± 0.00866)	1.0272 (± 0.00360)	1.0255 (± 0.00918)	1.0375 (± 0.00495)
Day 7	1.0233 (± 0.00686)	1.0250 (± 0.00522)	1.0273 (± 0.00327)	1.0265 (± 0.00919)

Notes:

[313] - Safety Population.

[314] - Safety Population.

[315] - Safety Population.

[316] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Urinalysis Parameter: Urobilinogen

End point title	Part 2: Absolute Values for Urinalysis Parameter:

End point description:

Urine samples were collected to analyze the urinalysis parameter: urobilinogen. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[317] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[318]	6[319]	6[320]	2[321]
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1)	3.40 (± 0.000)	3.40 (± 0.000)	3.40 (± 0.000)	3.40 (± 0.000)
Day 7	3.40 (± 0.000)	7.90 (± 6.971)	3.40 (± 0.000)	3.40 (± 0.000)

Notes:

[318] - Safety Population.

[319] - Safety Population.

[320] - Safety Population.

[321] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Urinalysis Parameter: pH

End point title	Part 2: Absolute Values for Urinalysis Parameter: pH[322]

End point description:

Urine samples were collected to analyze the urinalysis parameter: pH. Urine pH is an acid-base measurement. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acidic pH (5.0 - 6.0). Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[322] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[323]	6[324]	6[325]	2[326]
Units: pH				
arithmetic mean (standard deviation)				
Baseline (Day 1)	5.33 (± 0.258)	5.83 (± 0.753)	5.25 (± 0.418)	5.50 (± 0.000)
Day 7	5.50 (± 0.775)	5.67 (± 0.258)	5.33 (± 0.258)	5.75 (± 0.354)

Notes:

[323] - Safety Population.

[324] - Safety Population.

[325] - Safety Population.

[326] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for SBP and DBP

End point title	Part 1: Absolute Values for SBP and DBP[327]

End point description:

SBP and DBP were measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[327] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[328]	6[329]	2[330]	
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
Baseline (Day 1): SBP	120.2 (± 13.36)	121.8 (± 12.25)	106.0 (± 11.31)	
Days 8 to 10: SBP	117.7 (± 8.87)	122.3 (± 7.94)	104.5 (± 7.78)	
Baseline (Day 1): DBP	70.3 (± 17.32)	66.7 (± 10.80)	64.0 (± 5.66)	
Days 8 to 10: DBP	70.0 (± 6.81)	67.5 (± 9.91)	64.5 (± 4.95)	

Notes:

[328] - Safety Population.

[329] - Safety Population.

[330] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Respiratory Rate

End point title	Part 1: Absolute Values for Respiratory Rate[331]

End point description:

Respiratory rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[331] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[332]	6[333]	2[334]	
Units: Breaths per minute				
arithmetic mean (standard deviation)				
Baseline (Day 1)	16.0 (± 2.61)	16.2 (± 3.31)	15.0 (± 4.24)	
Days 8 to 10	15.0 (± 1.26)	16.3 (± 2.73)	14.0 (± 2.83)	

Notes:

[332] - Safety Population.

[333] - Safety Population.

[334] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for Pulse Rate

End point title	Part 1: Absolute Values for Pulse Rate[335]

End point description:

Pulse rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Days 8 to 10)

Notes:

[335] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[336]	6[337]	2[338]	
Units: Beats per minute				
arithmetic mean (standard deviation)				
Baseline (Day 1)	81.8 (± 18.25)	65.8 (± 14.22)	60.0 (± 2.83)	
Days 8 to 10	76.7 (± 21.13)	71.3 (± 11.93)	66.0 (± 5.66)	

Notes:

[336] - Safety Population.

[337] - Safety Population.

[338] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for SBP and DBP

End point title	Part 2: Absolute Values for SBP and DBP[339]

End point description:

SBP and DBP were measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[339] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[340]	6[341]	6[342]	2[343]
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
Baseline (Day 1): SBP	117.0 (± 7.95)	116.5 (± 11.04)	112.2 (± 9.93)	105.5 (± 2.12)
Day 7: SBP	118.0 (± 12.07)	114.3 (± 8.36)	119.5 (± 8.87)	106.5 (± 4.95)
Baseline (Day 1): DBP	71.5 (± 4.51)	74.0 (± 4.69)	71.8 (± 12.89)	71.0 (± 12.73)
Day 7: DBP	69.7 (± 4.50)	73.0 (± 5.06)	74.2 (± 5.27)	70.5 (± 4.95)

Notes:

[340] - Safety Population.

[341] - Safety Population.

[342] - Safety Population.

[343] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Respiratory Rate

End point title	Part 2: Absolute Values for Respiratory Rate[344]

End point description:

Respiratory rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[344] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[345]	6[346]	6[347]	2[348]
Units: Breaths per minute				
arithmetic mean (standard deviation)				
Baseline (Day 1)	17.3 (± 2.66)	17.2 (± 1.17)	17.2 (± 2.40)	16.0 (± 0.00)
Day 7	17.2 (± 2.56)	17.3 (± 2.07)	16.2 (± 2.23)	16.5 (± 2.12)

Notes:

[345] - Safety Population.

[346] - Safety Population.

[347] - Safety Population.

[348] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for Pulse Rate

End point title	Part 2: Absolute Values for Pulse Rate[349]

End point description:

Pulse rate was measured in the semi-supine position with a completely automated device after at least 5 minutes of rest for the participant in a quiet setting without distractions. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Visit 5 (Day 7)

Notes:

[349] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[350]	6[351]	6[352]	2[353]
Units: Beats per minute				
arithmetic mean (standard deviation)				
Baseline (Day 1)	68.3 (± 9.91)	74.5 (± 8.36)	77.0 (± 10.16)	64.5 (± 13.44)
Day 7	72.5 (± 16.34)	76.5 (± 7.87)	79.8 (± 12.45)	75.0 (± 5.66)

Notes:

[350] - Safety Population.

[351] - Safety Population.

[352] - Safety Population.

[353] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Values for ECG Parameters: PR, QRS, QT, QTcB and

QTcF intervals

End point title	Part 1: Absolute Values for ECG Parameters: PR, QRS, QT, QTcB and QTcF intervals[354]

End point description:

Twelve lead ECGs were obtained to measure PR interval, QRS duration, QT interval, QTcF interval and QTcB interval. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Visit 5 (Days 8 to 10: Pre-dose, 2, 4 and 6 hours)

Notes:

[354] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 1: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[355]	6[356]	2[357]	
Units: Milliseconds				
arithmetic mean (standard deviation)				
PR Interval- Baseline (Day 1)	136.6 (± 14.49)	168.4 (± 15.48)	176.5 (± 27.58)	
PR Interval- Days 8 to 10: Pre-dose	136.2 (± 15.26)	160.8 (± 19.60)	174.0 (± 29.70)	
PR Interval- Days 8 to 10: 2 hours	138.0 (± 14.46)	162.2 (± 11.53)	165.0 (± 28.28)	
PR Interval- Days 8 to 10: 4 hours	136.5 (± 12.10)	168.7 (± 13.81)	173.0 (± 28.28)	
PR Interval- Days 8 to 10: 6 hours	138.0 (± 9.10)	162.5 (± 15.06)	151.5 (± 23.33)	
QRS Duration- Baseline (Day 1)	93.1 (± 4.54)	95.7 (± 6.85)	85.8 (± 11.08)	
QRS Duration- Days 8 to 10: Pre-dose	90.0 (± 7.46)	92.3 (± 7.74)	80.5 (± 7.78)	
QRS Duration- Days 8 to 10: 2 hours	91.0 (± 6.36)	96.2 (± 7.17)	86.0 (± 7.07)	
QRS Duration- Days 8 to 10: 4 hours	89.8 (± 5.91)	94.0 (± 6.42)	84.5 (± 14.85)	
QRS Duration- Days 8 to 10: 6 hours	89.5 (± 7.04)	92.8 (± 10.11)	83.5 (± 2.12)	
QT Interval- Baseline (Day 1)	367.6 (± 26.04)	378.7 (± 26.75)	372.7 (± 29.70)	
QT Interval- Days 8 to 10: Pre-dose	368.3 (± 23.35)	376.0 (± 31.46)	353.0 (± 8.49)	
QT Interval- Days 8 to 10: 2 hours	365.2 (± 25.39)	383.2 (± 26.84)	344.0 (± 25.46)	
QT Interval- Days 8 to 10: 4 hours	376.3 (± 22.70)	387.7 (± 29.34)	347.5 (± 10.61)	
QT Interval- Days 8 to 10: 6 hours	373.3 (± 26.48)	384.5 (± 25.37)	348.5 (± 7.78)	
QTcB Interval- Baseline (Day 1)	412.15 (± 31.539)	397.75 (± 22.914)	388.43 (± 39.598)	
QTcB Interval- Days 8 to 10: Pre-dose	413.80 (± 42.176)	401.35 (± 22.923)	387.05 (± 33.163)	
QTcB Interval- Days 8 to 10: 2 hours	401.70 (± 37.316)	393.15 (± 26.290)	361.05 (± 7.283)	
QTcB Interval- Days 8 to 10: 4 hours	412.92 (± 42.143)	387.38 (± 24.454)	358.20 (± 12.162)	
QTcB Interval- Days 8 to 10: 6 hours	414.80 (± 34.569)	388.60 (± 23.893)	383.55 (± 28.496)	

QTcF Interval- Baseline (Day 1)	396.2 (± 17.67)	391.2 (± 19.11)	383.2 (± 36.06)	
QTcF Interval- Days 8 to 10: Pre-dose	397.3 (± 25.34)	392.3 (± 20.64)	375.5 (± 24.75)	
QTcF Interval- Days 8 to 10: 2 hours	388.7 (± 22.72)	389.8 (± 22.89)	355.5 (± 13.44)	
QTcF Interval- Days 8 to 10: 4 hours	399.8 (± 25.87)	387.5 (± 21.27)	354.5 (± 4.95)	
QTcF Interval- Days 8 to 10: 6 hours	400.2 (± 19.22)	387.3 (± 22.03)	371.0 (± 21.21)	

Notes:

[355] - Safety Population.

[356] - Safety Population.

[357] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Values for ECG Parameters: PR, QRS, QT, QTcB and QTcF intervals

End point title	Part 2: Absolute Values for ECG Parameters: PR, QRS, QT, QTcB and QTcF intervals[358]

End point description:

Twelve lead ECGs were obtained to measure PR interval, QRS duration, QT interval, QTcF interval and QTcB interval. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Visit 5 (Day 7: Pre-dose, 2, 4 and 6 hours)

Notes:

[358] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	Part 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[359]	6[360]	6[361]	2[362]
Units: Milliseconds				
arithmetic mean (standard deviation)				
PR Interval- Baseline (Day 1)	156.8 (± 33.02)	162.9 (± 29.73)	162.8 (± 20.83)	144.3 (± 6.13)
PR Interval- Day 7: Pre-dose	166.5 (± 25.62)	161.8 (± 31.06)	155.5 (± 26.10)	137.0 (± 5.66)
PR Interval- Day 7: 2 hours	162.8 (± 28.34)	160.5 (± 28.73)	159.7 (± 26.04)	150.5 (± 3.54)
PR Interval- Day 7: 4 hours	162.0 (± 24.85)	164.0 (± 31.51)	154.5 (± 20.51)	149.0 (± 11.31)
PR Interval- Day 7: 6 hours	160.7 (± 24.81)	160.7 (± 27.25)	160.7 (± 25.90)	136.5 (± 3.54)
QRS Duration- Baseline (Day 1)	92.6 (± 10.22)	95.1 (± 21.97)	88.9 (± 7.40)	85.7 (± 11.31)
QRS Duration- Day 7: Pre-dose	96.5 (± 8.14)	98.3 (± 28.86)	88.5 (± 3.99)	88.0 (± 4.24)
QRS Duration- Day 7: 2 hours	95.0 (± 9.78)	95.8 (± 19.29)	88.8 (± 4.49)	90.0 (± 12.73)
QRS Duration- Day 7: 4 hours	94.3 (± 8.89)	95.2 (± 18.94)	85.8 (± 4.88)	89.5 (± 7.78)

QRS Duration- Day 7: 6 hours	93.2 (± 10.61)	95.0 (± 21.29)	88.2 (± 8.11)	88.5 (± 17.68)
QT Interval- Baseline (Day 1)	386.6 (± 28.86)	355.9 (± 25.37)	362.5 (± 19.45)	378.8 (± 1.18)
QT Interval- Day 7: Pre-dose	379.2 (± 33.30)	354.3 (± 31.94)	367.5 (± 26.93)	382.0 (± 1.41)
QT Interval- Day 7: 2 hours	362.2 (± 31.24)	351.5 (± 25.05)	364.3 (± 17.32)	378.5 (± 4.95)
QT Interval- Day 7: 4 hours	373.8 (± 24.25)	360.2 (± 23.07)	360.8 (± 18.64)	390.0 (± 18.38)
QT Interval- Day 7: 6 hours	365.2 (± 34.53)	361.8 (± 25.88)	363.2 (± 19.50)	381.5 (± 6.36)
QTcB Interval- Baseline (Day 1)	402.88 (± 26.814)	398.24 (± 25.587)	411.18 (± 15.858)	406.73 (± 20.742)
QTcB Interval- Day 7: Pre-dose	398.72 (± 26.663)	398.58 (± 21.075)	414.63 (± 17.816)	399.65 (± 18.173)
QTcB Interval- Day 7: 2 hours	405.78 (± 10.923)	398.33 (± 33.672)	406.30 (± 27.565)	388.50 (± 17.819)
QTcB Interval- Day 7: 4 hours	395.92 (± 22.851)	397.68 (± 20.635)	412.48 (± 27.377)	382.90 (± 17.961)
QTcB Interval- Day 7: 6 hours	399.62 (± 19.074)	402.42 (± 22.916)	409.50 (± 19.009)	396.90 (± 3.253)
QTcF Interval- Baseline (Day 1)	397.4 (± 24.60)	383.5 (± 23.72)	394.1 (± 12.71)	397.3 (± 13.67)
QTcF Interval- Day 7: Pre-dose	391.5 (± 24.01)	383.0 (± 24.90)	398.2 (± 18.58)	394.0 (± 12.73)
QTcF Interval- Day 7: 2 hours	390.2 (± 12.16)	382.2 (± 30.20)	391.8 (± 22.44)	385.0 (± 14.14)
QTcF Interval- Day 7: 4 hours	388.0 (± 18.21)	384.7 (± 20.42)	394.7 (± 18.91)	385.0 (± 18.38)
QTcF Interval- Day 7: 6 hours	387.8 (± 11.29)	388.0 (± 21.76)	393.3 (± 17.20)	391.5 (± 4.95)

Notes:

[359] - Safety Population.

[360] - Safety Population.

[361] - Safety Population.

[362] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Area under the plasma concentration time curve from zero to 24 (AUC[0-24]) following administration of GSK3640254 on Day 1

End point title	Part 1: Area under the plasma concentration time curve from zero to 24 (AUC[0-24]) following administration of GSK3640254 on Day 1[363]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Pharmacokinetic (PK) Population consisted of all participants who received GSK3640254 and underwent plasma PK sampling during the study. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[363] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5[364]	6[365]		
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.6946 (± 13.5)	12.3929 (± 91.3)		

Notes:

[364] - PK Population.

[365] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Maximum observed concentration (Cmax) following administration of GSK3640254 on Day 1

End point title	Part 1: Maximum observed concentration (Cmax) following administration of GSK3640254 on Day 1[366]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[366] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[367]	6[368]		
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0591 (± 177.4)	0.9381 (± 82.3)		

Notes:

[367] - PK Population.

[368] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Time to maximum observed concentration (Tmax) following administration of GSK3640254 on Day 1

End point title	Part 1: Time to maximum observed concentration (Tmax) following administration of GSK3640254 on Day 1[369]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[369] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[370]	6[371]		
Units: Hours				
median (full range (min-max))	2.9250 (0.000 to 5.000)	5.5250 (3.917 to 8.050)		

Notes:

[370] - PK Population.

[371] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Concentration at 24 hours post-dose (C24) following administration of GSK3640254 on Day 1

End point title	Part 1: Concentration at 24 hours post-dose (C24) following administration of GSK3640254 on Day 1[372]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[372] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[373]	6[374]		
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0180 (± 27.5)	0.3553 (± 92.7)		

Notes:

[373] - PK Population.

[374] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absorption lag time (Tlag) following administration of GSK3640254 on Day 1

End point title	Part 1: Absorption lag time (Tlag) following administration of GSK3640254 on Day 1[375]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[375] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[376]	6[377]		
Units: Hours				
median (full range (min-max))	0.500 (0.00 to 1.00)	0.000 (0.00 to 1.00)		

Notes:

[376] - PK Population.

[377] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: AUC(0-24) following administration of GSK3640254 on Day 1

End point title	Part 2: AUC(0-24) following administration of GSK3640254 on Day 1[378]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[378] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[379]	6[380]	6[381]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)	3.2527 (± 31.7)	6.1228 (± 38.8)	14.0335 (± 36.6)	

Notes:

[379] - PK Population.

[380] - PK Population.

[381] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Cmax following administration of GSK3640254 on Day 1

End point title	Part 2: Cmax following administration of GSK3640254 on Day 1[382]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[382] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[383]	6[384]	6[385]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.2316 (± 30.5)	0.4329 (± 33.6)	0.9178 (± 41.5)	

Notes:

[383] - PK Population.

[384] - PK Population.

[385] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Tmax following administration of GSK3640254 on Day 1

End point title	Part 2: Tmax following administration of GSK3640254 on Day

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[386] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[387]	6[388]	6[389]	
Units: Hours				
median (full range (min-max))	4.4167 (3.967 to 8.000)	4.0750 (2.950 to 6.167)	5.5083 (3.000 to 6.250)	

Notes:

[387] - PK Population.

[388] - PK Population.

[389] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: C24 following administration of GSK3640254 on Day 1

End point title	Part 2: C24 following administration of GSK3640254 on Day

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[390] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[391]	6[392]	6[393]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0951 (± 33.7)	0.1856 (± 36.2)	0.4207 (± 33.8)	

Notes:

[391] - PK Population.

[392] - PK Population.

[393] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Tlag following administration of GSK3640254 on Day 1

End point title	Part 2: Tlag following administration of GSK3640254 on Day

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[394] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[395]	6[396]	6[397]	
Units: Hours				
median (full range (min-max))	0.483 (0.00 to 2.00)	0.000 (0.00 to 1.00)	0.000 (0.00 to 1.00)	

Notes:

[395] - PK Population.

[396] - PK Population.

[397] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Area under the plasma drug concentration-time curve from pre-dose to the end of the dosing interval at steady state (AUC[0-tau]) following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Area under the plasma drug concentration-time curve from pre-dose to the end of the dosing interval at steady state (AUC[0-tau]) following repeat dose administration of GSK3640254 on Days 8 to 10[398]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[398] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[399]	6[400]		
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.9082 (± 44.7)	27.9363 (± 18.4)		

Notes:

[399] - PK Population.

[400] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Cmax following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Cmax following repeat dose administration of GSK3640254 on Days 8 to 10[401]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[401] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[402]	6[403]		
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0549 (± 41.3)	1.8559 (± 19.5)		

Notes:

[402] - PK Population.

[403] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Tmax following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Tmax following repeat dose administration of GSK3640254 on Days 8 to 10[404]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[404] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[405]	6[406]		
Units: Hours				
median (full range (min-max))	4.0167 (1.867 to 5.000)	5.4833 (3.000 to 6.200)		

Notes:

[405] - PK Population.

[406] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Pre-dose concentration (C0) following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Pre-dose concentration (C0) following repeat dose administration of GSK3640254 on Days 8 to 10[407]

End point description:

Blood sample was collected at indicated time point for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose

Notes:

[407] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[408]	5[409]		
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0268 (± 41.6)	0.6928 (± 33.6)		

Notes:

[408] - PK Population.

[409] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Concentration at end of dosing interval (Ctau) following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Concentration at end of dosing interval (Ctau) following repeat dose administration of GSK3640254 on Days 8 to 10[410]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[410] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[411]	6[412]		
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.0267 (± 47.0)	0.7033 (± 29.6)		

Notes:

[411] - PK Population.

[412] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Apparent terminal phase half-life (t1/2) following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Apparent terminal phase half-life (t1/2) following repeat dose administration of GSK3640254 on Days 8 to 10[413]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. 99999 indicates that, t1/2 could not be calculated as the criteria of a span ratio [ratio of half-life to time used for half-life calculation] for at least 2 participants could not be fulfilled due to lack of available data.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[413] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[414]	6[415]		
Units: Hours				
median (full range (min-max))	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Notes:

[414] - PK Population.

[415] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Apparent oral clearance (CL/F) following repeat dose administration of GSK3640254 on Days 8 to 10

End point title	Part 1: Apparent oral clearance (CL/F) following repeat dose administration of GSK3640254 on Days 8 to 10[416]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[416] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[417]	6[418]		
Units: Milliliter per hour				
geometric mean (geometric coefficient of variation)	11010.5393 (± 44.7)	7159.1443 (± 18.4)		

Notes:

[417] - PK Population.

[418] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: AUC(0-tau) following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: AUC(0-tau) following repeat dose administration of GSK3640254 on Day 7[419]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[419] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[420]	6[421]	6[422]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)	7.4626 (± 26.8)	11.8256 (± 26.7)	29.2952 (± 27.9)	

Notes:

[420] - PK Population.

[421] - PK Population.

[422] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Cmax following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: Cmax following repeat dose administration of GSK3640254 on Day 7[423]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[423] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[424]	6[425]	6[426]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.4692 (± 20.6)	0.7470 (± 23.7)	1.8574 (± 26.0)	

Notes:

[424] - PK Population.

[425] - PK Population.

[426] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Tmax following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: Tmax following repeat dose administration of GSK3640254 on Day 7[427]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[427] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[428]	6[429]	6[430]	
Units: Hours				
median (full range (min-max))	4.0583 (2.000 to 8.000)	4.5750 (4.000 to 5.183)	4.0750 (2.917 to 5.200)	

Notes:

[428] - PK Population.

[429] - PK Population.

[430] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: C0 following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: C0 following repeat dose administration of GSK3640254 on Day 7[431]

End point description:

Blood sample was collected at indicated time point for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose

Notes:

[431] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[432]	6[433]	6[434]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.2155 (± 24.2)	0.3575 (± 38.0)	0.7520 (± 38.8)	

Notes:

[432] - PK Population.

[433] - PK Population.

[434] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Ctau following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: Ctau following repeat dose administration of GSK3640254 on Day 7[435]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[435] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[436]	6[437]	6[438]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)	0.2187 (± 30.1)	0.3599 (± 31.1)	0.7979 (± 34.1)	

Notes:

[436] - PK Population.

[437] - PK Population.

[438] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: t1/2 following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: t1/2 following repeat dose administration of GSK3640254 on Day 7[439]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. 99999 indicates that, t1/2 could not be calculated as the criteria of a span ratio [ratio of half-life to time used for half-life calculation] for at least 2 participants could not be fulfilled due to lack of available data.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[439] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[440]	6[441]	6[442]	
Units: Hours				
median (full range (min-max))	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	

Notes:

[440] - PK Population.

[441] - PK Population.

[442] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: CL/F following repeat dose administration of GSK3640254 on Day 7

End point title	Part 2: CL/F following repeat dose administration of GSK3640254 on Day 7[443]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis.

End point type	Secondary

End point timeframe:

Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[443] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[444]	6[445]	6[446]	
Units: Milliliter per hour				
geometric mean (geometric coefficient of variation)	5360.0526 (± 26.8)	6764.9862 (± 26.7)	4778.9430 (± 27.9)	

Notes:

[444] - PK Population.

[445] - PK Population.

[446] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 AUC(0-tau)

End point title	Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 AUC(0-tau)[447]

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Baseline value was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Statistical analysis for relationship between PK parameters (AUC) and PD measures (Change from Baseline in plasma HIV-1 RNA) were explored using a frequentist three parameter Emax non-linear model. The model parameters estimated included: maximum response (Emax), PK parameter value that attains 50 percent (%) of the maximal effect (EC50) and residual variability (s2e). PK/PD Population consisted of participants who met criteria for Per-Protocol and Pharmacokinetic Population analysis sets and who underwent PD sampling during the study.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Day 8

Notes:

[447] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[448]	6[449]	6[450]	6[451]
Units: Copies per milliliter				
arithmetic mean (standard deviation)	12071.4 (± 42117.29)	-113331.4 (± 89475.00)	-48655.0 (± 26269.41)	-37904.3 (± 38814.54)

Notes:

[448] - PK/PD Population.

[449] - PK/PD Population.

[450] - PK/PD Population.

[451] - PK/PD Population.

End point values	Part 2: GSK3640254 140 mg			
Subject group type	Reporting group			
Number of subjects analysed	6[452]			
Units: Copies per milliliter				
arithmetic mean (standard deviation)	-64861.5 (± 83728.15)			

Notes:
[452] - PK/PD Population.

Statistical analyses

Statistical analysis title	Statistical Analysis of Emax
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Emax
Point estimate	-1.937
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.484
upper limit	-1.389

Statistical analysis title	Statistical Analysis of EC50
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	EC50
Point estimate	7.094
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.585
upper limit	13.602

Statistical analysis title	Statistical Analysis of s2e
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	s2e
Point estimate	0.137
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.062
upper limit	0.212

Secondary: Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 Cmax

End point title	Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 Cmax[453]

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Baseline value was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Statistical analysis for relationship between PK parameters (Cmax) and PD measures (Change from Baseline in plasma HIV-1 RNA) were explored using a frequentist three parameter Emax non-linear model. The model parameters estimated included: Emax, EC50 and s2e.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Day 8

Notes:

[453] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[454]	6[455]	6[456]	6[457]
Units: Copies per milliliter				
arithmetic mean (standard deviation)	12071.4 (± 42117.29)	-113331.4 (± 89475.00)	-48655.0 (± 26269.41)	-37904.3 (± 38814.54)

Notes:

[454] - PK/PD Population.

[455] - PK/PD Population.

[456] - PK/PD Population.

[457] - PK/PD Population.

End point values	Part 2: GSK3640254 140 mg			
Subject group type	Reporting group			
Number of subjects analysed	6[458]			
Units: Copies per milliliter				
arithmetic mean (standard deviation)	-64861.5 (± 83728.15)			

Notes:
[458] - PK/PD Population.

Statistical analyses

Statistical analysis title	Statistical Analysis of Emax
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Emax
Point estimate	-1.929
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.479
upper limit	-1.379

Statistical analysis title	Statistical Analysis of EC50
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	EC50
Point estimate	0.446
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	0.861

Statistical analysis title	Statistical Analysis of s2e
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	s2e
Point estimate	0.139
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.063
upper limit	0.216

Secondary: Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 Ctau

End point title	Part 1 and Part 2: Change From Baseline in Plasma HIV-1 RNA Relative to Day 8 Ctau[459]

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Baseline value was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Statistical analysis for relationship between PK parameters (Ctau) and PD measures (Change from Baseline in plasma HIV-1 RNA) were explored using a frequentist three parameter Emax non-linear model. The model parameters estimated included: Emax, EC50 and s2e.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Day 8

Notes:

[459] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[460]	6[461]	6[462]	6[463]
Units: Copies per milliliter				
arithmetic mean (standard deviation)	12071.4 (± 42117.29)	-113331.4 (± 89475.00)	-48655.0 (± 26269.41)	-37904.3 (± 38814.54)

Notes:

[460] - PK/PD Population.

[461] - PK/PD Population.

[462] - PK/PD Population.

[463] - PK/PD Population.

End point values	Part 2: GSK3640254 140 mg			
Subject group type	Reporting group			
Number of subjects analysed	6[464]			
Units: Copies per milliliter				
arithmetic mean (standard deviation)	-64861.5 (± 83728.15)			

Notes:
[464] - PK/PD Population.

Statistical analyses

Statistical analysis title	Statistical Analysis of Emax
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Emax
Point estimate	-1.926
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.498
upper limit	-1.354

Statistical analysis title	Statistical Analysis of EC50
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	EC50
Point estimate	0.197
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.007
upper limit	0.386

Statistical analysis title	Statistical Analysis of s2e
Comparison groups	Part 1: GSK3640254 10 mg v Part 1: GSK3640254 200 mg v Part 2: GSK3640254 40 mg v Part 2: GSK3640254 80 mg v Part 2: GSK3640254 140 mg

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	s2e
Point estimate	0.144
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.065
upper limit	0.222

Secondary: Part 1: Accumulation ratio following repeat dose administration of GSK3640254

End point title	Part 1: Accumulation ratio following repeat dose administration of GSK3640254[465]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The accumulation ratios (Ro) were calculated as Ro_AUC equal to (=) AUC(0-tau) Days 8 to 10 divided by (/) AUC(0-24) Day 1; Ro_Cmax=Cmax Days 8 to 10/Cmax Day 1; and Ro_Ctau=Ctau Days 8 to 10/C24 Day 1. Only those participants with data available at the specified time points were analyzed (indicated by n=X in category titles).

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose; Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[465] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 1: GSK3640254 10 mg	Part 1: GSK3640254 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[466]	6[467]		
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ro_AUC(0-tau), n=5,6	1.5352 (± 24.5)	2.2542 (± 72.1)		
Ro_Cmax, n=6,6	0.9287 (± 171.7)	1.9785 (± 69.4)		
Ro_Ctau, n=6,6	1.4790 (± 22.2)	1.9796 (± 61.2)		

Notes:

[466] - PK Population.

[467] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Accumulation ratio following repeat dose administration of GSK3640254

End point title	Part 2: Accumulation ratio following repeat dose administration of GSK3640254[468]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The accumulation ratios (Ro) were calculated as Ro_AUC=AUC(0-tau) Day 7/AUC(0-24) Day 1; Ro_Cmax=Cmax Day 7/Cmax Day 1; and Ro_Ctau=Ctau Day 7/C24 Day 1.

End point type	Secondary

End point timeframe:

Days 1 and 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

Notes:

[468] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part 2: GSK3640254 40 mg	Part 2: GSK3640254 80 mg	Part 2: GSK3640254 140 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[469]	6[470]	6[471]	
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ro_AUC(0-tau)	2.2943 (± 11.2)	1.9314 (± 18.6)	2.0875 (± 29.2)	
Ro_Cmax	2.0258 (± 24.4)	1.7258 (± 17.6)	2.0236 (± 37.5)	
Ro_Ctau	2.2985 (± 6.4)	1.9389 (± 20.8)	1.8967 (± 16.0)	

Notes:

[469] - PK Population.

[470] - PK Population.

[471] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on AUC(0-24)

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on AUC(0-24)

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	1.018 (0.876 to 1.160)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on Cmax

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on Cmax

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	0.964 (0.774 to 1.154)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on C24

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 administered on Day 1 based on C24

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Day 1: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	1.061 (0.924 to 1.199)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on AUC(0-tau)

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on AUC(0-tau)

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose; Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	1.179 (1.074 to 1.283)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on Cmax

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on Cmax

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose; Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	1.204 (1.107 to 1.302)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on Ctau

End point title	Part 1 and Part 2: Dose proportionality of GSK3640254 following repeat dose administration based on Ctau

End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of GSK3640254. The PK parameters were calculated by standard non-compartmental analysis. Dose proportionality was assessed using Power model with logarithm of dose as fixed effect. Slope and 90% confidence interval for the slope are presented.

End point type	Secondary

End point timeframe:

Days 8 to 10: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose; Day 7: Pre-dose and 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours post-dose

End point values	GSK3640254 10 mg to 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Slope of log dose				
number (confidence interval 90%)	1.137 (1.018			

to 1.257)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part 1: up to Day 24; Part 2: up to Day 12

Adverse event reporting additional description:

Safety Population consisted of all participants who were enrolled into the study with documented evidence of having received at least 1 dose of randomized treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Part 1: GSK3640254 200 mg

Reporting group description:

Participants received GSK3640254 200 mg, capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Reporting group title	Part 1: GSK3640254 10 mg

Reporting group description:

Participants received GSK3640254 10 mg, capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Reporting group title	Part 1: Placebo

Reporting group description:

Participants received placebo capsules, orally for 10 days. Participants were followed for up to 14 days post last dose of study treatment.

Reporting group title	Part 2: GSK3640254 40 mg

Reporting group description:

Participants received GSK3640254 40 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Reporting group title	Part 2: Placebo

Reporting group description:

Participants received placebo capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Reporting group title	Part 2: GSK3640254 80 mg

Reporting group description:

Participants received GSK3640254 80 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Reporting group title	Part 2: GSK3640254 140 mg

Reporting group description:

Participants received GSK3640254 140 mg, capsules, orally for 7 days. Participants were followed for up to 5 days post last dose of study treatment.

Serious adverse events	Part 1: GSK3640254 200 mg	Part 1: GSK3640254 10 mg	Part 1: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Cardiac disorders			
Congestive cardiomyopathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: GSK3640254 40 mg	Part 2: Placebo	Part 2: GSK3640254 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Cardiac disorders			
Congestive cardiomyopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: GSK3640254 140 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Cardiac disorders			
Congestive cardiomyopathy			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1: GSK3640254 200 mg	Part 1: GSK3640254 10 mg	Part 1: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	3 / 6 (50.00%)	0 / 2 (0.00%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Neutropenia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Catarrh			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Meningococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Insulin resistance			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part 2: GSK3640254 40 mg	Part 2: Placebo	Part 2: GSK3640254 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	0 / 2 (0.00%)	4 / 6 (66.67%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			

subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Vomiting			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Meningococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2: GSK3640254 140 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)		

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Migraine			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nodule			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Catarrh			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pruritus			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Meningococcal infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			

Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Insulin resistance subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 September 2018	Amendment 1: The original version of the protocol was not submitted to any health authority (HA) worldwide. Key elements of the original protocol design were discussed with the United States Food and Drug Administration (US FDA) in the context of pre-Investigational New Drug (IND) feedback (i.e. scientific advice). To this end, the overall design, duration, and sample population remain the same. However, minor changes were made to exclusion criteria, participant monitoring, and reasons for discontinuation to enhance the safety of trial participants. Finally, other administrative changes and updates were made (e.g. succinct results from two Phase 1 clinical trials in healthy volunteers).
10 January 2019	Amendment 2: Feedback from a Health Authority has provided greater specificity and clarification to existing exclusion criteria on psychiatric disease. Additionally, we have clarified that participants who are recently infected with HIV-1 should be excluded. Next, the human PK data available from Study 207187 Single ascending dose/Multiple ascending dose (SAD/MAD) resulted in the removal of contraceptive requirements of male participants and any pregnancy monitoring requirements of female partners (of male participants). Further clarification on prohibited concomitant medications was provided. Finally, minor changes/clarifications were made to participant monitoring and reasons for discontinuation.
26 August 2019	Amendment 3: Data from Part 1 showed a decline in Human immunodeficiency virus-1 (HIV-1) Ribonucleic Acid (RNA) and reasonable pharmacokinetic (PK) profile. There were no clinically significant trends in adverse events (AEs), vital signs, electrocardiogram (ECG) findings, or chemistry/haematology laboratory abnormalities across dosing arms. However, some participants receiving GSK3640254 had treatment emergent resistance mutations associated with maturation inhibitors observed on or after Day 11 (after 10 days of receiving GSK3640254 monotherapy). Additionally, no resistance to existing and commercially available classes of antiretroviral medications (e.g., reverse transcriptase, protease, integrase) was observed at Day 11 as there is no known cross-resistance between maturation inhibitors and other classes of anti-retrovirals (ARVs). Genotypic analysis of samples at Clinic Visit 5 (Study Day 8 or 9) revealed no treatment emergent resistance. As a result, Sponsor made two substantial changes to decrease the risk of treatment emergent resistance to participants in Part 2: 1) decrease the duration of monotherapy from 10 days to 7 days based on the interim genotypic analysis, and 2) start Investigator selected combination anti-retroviral therapy (cART) immediately after completion of monotherapy and the Part 2 primary endpoint (i.e., after the collection of HIV-1 RNA on Day 8).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported