



Clinical trial results:

A 52-week, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multi-centre Study of the Efficacy and Safety of GSK3511294 Adjunctive Therapy in Adult and Adolescent Participants With Severe Uncontrolled Asthma With an Eosinophilic Phenotype

Summary

EudraCT number	2020-003632-25
Trial protocol	DE FR CZ PL IT ES IE
Global end of trial date	21 November 2023

Results information

Result version number	v2
This version publication date	16 October 2024
First version publication date	06 June 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	206713
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04719832
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 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	15 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 November 2023
Global end of trial reached?	Yes
Global end of trial date	21 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of GSK3511294 100 mg (SC) every 26 weeks versus placebo in participants with severe uncontrolled asthma with an eosinophilic phenotype on top of existing asthma therapy

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czechia: 34
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Germany: 38
Country: Number of subjects enrolled	Ireland: 3
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Poland: 74
Country: Number of subjects enrolled	Spain: 74
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	United States: 62
Country: Number of subjects enrolled	Canada: 9
Country: Number of subjects enrolled	China: 59
Country: Number of subjects enrolled	Russian Federation: 21
Worldwide total number of subjects	395
EEA total number of subjects	232

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)	8
Adults (18-64 years)	287
From 65 to 84 years	100
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Of 395 participants who were randomized, 382 participants were included in Full analysis set (FAS) population. FAS included all randomized participants who received at least 1 dose of study drug excluding 11 participants from 1 GCP violation site. Two participants were randomized in error & did not receive any study drug.

Pre-assignment

Screening details:

In this study, out of 622 participants screened, 395 participants were randomized to the study. In total 382 participants received at least one dose of study drug & included in the FAS.

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching Placebo once every 26 weeks

Arm title	GSK3511294
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Arm description:

Participants received a 100 milligram (mg) dose of GSK3511294 SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

Arm type	Experimental
Investigational medicinal product name	GSK3511294
Investigational medicinal product code	
Other name	Depemokimab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100 milligram (mg) once every 26 weeks

Number of subjects in period 1^[1]	Placebo	GSK3511294
Started	132	250
Completed	122	237
Not completed	10	13
Consent withdrawn by subject	5	5
Physician decision	-	1
Adverse event, non-fatal	2	-
Pregnancy	1	1
Lost to follow-up	-	2
Lack of efficacy	2	4

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Of 395 participants who were randomized, 11 participants from one of the site were excluded from the full analysis population due to data integrity concerns & GCP violations, and two randomized participants did not receive any study treatment. A total of 382 participants received treatment and were included in the Full analysis set population

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received placebo subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.

Reporting group title	GSK3511294
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Reporting group description:

Participants received a 100 milligram (mg) dose of GSK3511294 SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

Reporting group values	Placebo	GSK3511294	Total
Number of subjects	132	250	382
Age categorical			
Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	5	3	8
Adults (18-64 years)	91	185	276
From 65-84 years	36	62	98
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	53.6	54.1	
standard deviation	± 14.91	± 13.82	-
Sex: Female, Male			
Units: Participants			
Female	79	144	223
Male	53	106	159
Race/Ethnicity, Customized			
Units: Subjects			
De-Identified	23	43	66
WHITE	109	207	316

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants received placebo subcutaneous (SC) injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma standard of care (SOC) treatment throughout the study.	
Reporting group title	GSK3511294
Reporting group description: Participants received a 100 milligram (mg) dose of GSK3511294 SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.	

Primary: Annualized Rate of Clinically Significant Exacerbations Over 52 Weeks

End point title	Annualized Rate of Clinically Significant Exacerbations Over 52 Weeks
End point description: Clinically significant exacerbations of asthma were defined as worsening of asthma which required use of systemic corticosteroids (CSs) and/or hospitalization and/or Emergency Department (ED) visit. For all participants, IV or oral steroids (e.g., prednisone) for at least 3 days or a single IM CS dose is required. For participants on maintenance systemic CSs, at least double the existing maintenance dose for at least 3 days is required. Exacerbations occurring from the start of randomized study treatment up to the Week 52 visit, including exacerbations reported after early discontinuation from study treatment by participants who remained in the study, were included in the analysis. Annualized rate of exacerbations was analyzed using a generalized linear model assuming a negative binomial distribution. The analysis was performed on the Full Analysis Set population.	
End point type	Primary
End point timeframe: From first dose of study treatment up to Week 52	

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	249		
Units: Exacerbation per participant per year				
number (confidence interval 95%)	1.11 (0.86 to 1.43)	0.46 (0.36 to 0.58)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: To demonstrate the superiority of GSK3511294 100 mg SC + SoC following two doses (at Week 0 and at Week 26) compared with placebo + SoC, assessed by the annualized rate of clinically significant exacerbations measured over the study intervention period of 52 weeks.	
Comparison groups	Placebo v GSK3511294

Number of subjects included in analysis	381
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	< 0.001
Method	Negative binomial distribution
Parameter estimate	Rate Ratio
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.59

Notes:

[1] - Analysis performed using a negative binomial model with covariates of treatment, exacerbation history (2, 3, 4+), baseline ICS dose (medium, high), geographical region, baseline percent predicted FEV1, and offset of log (total time in the study in years)

Secondary: Change From Baseline in St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 52

End point title	Change From Baseline in St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 52
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End point description:

The SGRQ is a 50-item patient-reported outcome tool used to measure Quality of Life in participants with airway obstruction diseases. The questions are designed to be self-completed by the participant. The total score was calculated by the symptom score, activity and impact score; and summarizing the impact of the disease on overall health status. Scores are expressed as a percentage of overall impairment where 100 representing worst possible health status and 0 indicating best possible health status. Higher scores also indicating greater impairment of quality of life. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the Full Analysis set population.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 52

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	240		
Units: Scores on a scale				
least squares mean (standard error)	-9.67 (± 1.544)	-13.03 (± 1.112)		

Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline SGRQ total score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline SGRQ total score and visit by treatment group

Comparison groups	Placebo v GSK3511294
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Number of subjects included in analysis	368
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.08
Method	Mixed Models Repeated Measures (MMRM)
Parameter estimate	Difference in Least Square Means
Point estimate	-3.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.11
upper limit	0.39

Secondary: Change From Baseline in Asthma Control Questionnaire-5 (ACQ-5) Score at Week 52

End point title	Change From Baseline in Asthma Control Questionnaire-5 (ACQ-5) Score at Week 52
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End point description:

The ACQ-5 is a five-item questionnaire developed as a measure of participants asthma symptom control. The questions are designed to be self-completed by the participant. The 5 questions enquired to recall how their asthma had been during the previous week and to respond about the frequency and/or severity of symptoms (nocturnal awakening on waking in the morning, activity limitation, and shortness of breath, wheeze). The overall ACQ-5 response option is the mean score of all 5 questions representing 0 with no impairment/limitation & 6 as total impairment/ limitation. Higher scores indicated more limitations and lower score with better asthma control. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the Full Analysis set population.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 52

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	241		
Units: Scores on a Scale				
least squares mean (standard error)	-0.77 (± 0.091)	-0.82 (± 0.066)		

Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ACQ-5 score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ACQ-5 score and visit by treatment group.

Comparison groups	Placebo v GSK3511294
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Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69
Method	Mixed Models Repeated Measures (MMRM)
Parameter estimate	Difference in Least Square Means
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.18

Secondary: Change From Baseline in Pre-Bronchodilator Forced Expiratory Volume in One Second (FEV1) At Week 52

End point title	Change From Baseline in Pre-Bronchodilator Forced Expiratory Volume in One Second (FEV1) At Week 52
End point description:	
FEV1 is defined as the maximum volume of air that can be forced out in one second after taking a deep breath by a person. FEV1 was measured using spirometry. Change from Baseline in clinic pre-bronchodilator FEV1 will be determined. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed on the Full Analysis set population.	
End point type	Secondary
End point timeframe:	
Baseline (Day 1) and Week 52	

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	236		
Units: Scores on a Scale				
least squares mean (standard error)	0.160 (± 0.0364)	0.160 (± 0.0263)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline pre-bronchodilator FEV1, visit, visit by baseline pre-bronchodilator FEV1 and visit by treatment group.	
Comparison groups	Placebo v GSK3511294

Number of subjects included in analysis	362
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.991
Method	Mixed Models Repeated Measures (MMRM)
Parameter estimate	Difference in Least Square Means
Point estimate	-0.001
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.089
upper limit	0.088

Secondary: Change From Baseline in Asthma Nighttime Symptom Diary (ANSD) Weekly Mean Score at Week 52

End point title	Change From Baseline in Asthma Nighttime Symptom Diary (ANSD) Weekly Mean Score at Week 52
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End point description:

The ANSD is a 6-item self-administered patient-reported diary developed by the patient related outcomes (PRO) Consortium's Asthma Working Group (in accordance with the Food and Drug Administration's PRO Guidance) to facilitate comprehensive and reliable assessment of asthma symptoms from a participant's perspective. ANSD was to be completed upon waking and refers to asthma symptoms during the previous night. Participants were required to score based on 6 patient-reported symptoms as difficulty breathing, wheezing, shortness of breath, chest tightness, chest pain, and cough at their worst during the respective timeframes using an 11-point numeric rating scale (NRS) ranging from 0 (None) to 10 (As bad as you can imagine). Higher scores indicate more severe symptoms. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed for participants in the FAS population for whom at least one ADSD/ANSD questionnaire were administered.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 52

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	185		
Units: Scores on a Scale				
least squares mean (standard error)				
Asthma Nighttime Symptom Diary (ANSD), n=51,95	-1.30 (± 0.168)	-1.39 (± 0.120)		

Statistical analyses

Statistical analysis title	Statistical Analysis for ANSD
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Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ADSD weekly mean score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ADSD weekly

mean score and visit by treatment group.

Comparison groups	Placebo v GSK3511294
Number of subjects included in analysis	280
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	Mixed Models Repeated Measures (MMRM)
Parameter estimate	Difference in Least Square Means
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.31

Secondary: Change From Baseline in Asthma Daily Symptom Diary (ADSD) Weekly Mean Score at Week 52

End point title	Change From Baseline in Asthma Daily Symptom Diary (ADSD) Weekly Mean Score at Week 52
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End point description:

The ADSD is a 6-item self-administered patient-reported diary developed by the patient related outcomes (PRO) Consortium's Asthma Working Group (in accordance with the Food and Drug Administration's PRO Guidance) to facilitate comprehensive and reliable assessment of asthma symptoms from a participant's perspective. ADSD was to be completed before going to bed and refers to asthma symptoms during the day. Participants were required to score based on 6 patient-reported symptoms as difficulty breathing, wheezing, shortness of breath, chest tightness, chest pain, and cough at their worst during the respective timeframes using an 11-point numeric rating scale (NRS) ranging from 0 (None) to 10 (As bad as you can imagine). Higher scores indicate more severe symptoms. Change from Baseline was defined as value at the indicated time point minus Baseline value. The analysis was performed for participants in the FAS population for whom at least one ADSD/ANSD questionnaire were administered.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 52

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	206		
Units: Scores on a Scale				
least squares mean (standard error)	-1.25 (± 0.140)	-1.33 (± 0.101)		

Statistical analyses

Statistical analysis title	Statistical Analysis for ADSD
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Statistical analysis description:

Analysis performed using a repeated measures model with covariates of treatment group, baseline ICS

dose (medium or high), exacerbation history (2, 3, 4+), geographical region, baseline ADSD weekly mean score, baseline pre-bronchodilator percent predicted FEV1, visit, visit by baseline ADSD weekly mean score and visit by treatment group.

Comparison groups	Placebo v GSK3511294
Number of subjects included in analysis	316
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.647
Method	Mixed Models Repeated Measures (MMRM)
Parameter estimate	Difference in Least Square Means
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.26

Secondary: Annualized Rate of Exacerbations Requiring Hospitalization and/or Emergency Department (ED) Visit Over 52 Weeks

End point title	Annualized Rate of Exacerbations Requiring Hospitalization and/or Emergency Department (ED) Visit Over 52 Weeks
End point description:	Exacerbations requiring hospitalization and/or ED visit are reported here. The data did not meet the condition (total of 20 or more exacerbations requiring hospitalization and/or ED visit) for conducting the statistical analysis. The assessment was performed on the Full Analysis set population.
End point type	Secondary
End point timeframe:	Up to Week 52

End point values	Placebo	GSK3511294		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	250		
Units: Number	13	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs), deaths (all causes) and non-serious adverse events (non-SAEs) were collected from the start of the study intervention till follow up week 56.

Adverse event reporting additional description:

SAEs, deaths and non-SAEs were reported for the Safety Population which included all participants who received at least 1 dose of study treatment excluding participants from one study site due to concerns about data integrity and GCP violation.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	GSK3511294
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Reporting group description:

Participants received a 100 mg dose of GSK3511294 SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

Reporting group title	Placebo
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Reporting group description:

Participants received placebo SC injection once every 26 weeks (week 0 and week 26). Participants were to be maintained on their existing baseline maintenance asthma SOC treatment throughout the study.

Serious adverse events	GSK3511294	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 250 (6.00%)	22 / 132 (16.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			

subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Mass			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Genital prolapse			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	3 / 250 (1.20%)	5 / 132 (3.79%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular disorder			

subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Rhegmatogenous retinal detachment			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cholelithiasis			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Joint range of motion decreased			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 250 (0.40%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 250 (0.00%)	1 / 132 (0.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

COVID-19			
subjects affected / exposed	0 / 250 (0.00%)	2 / 132 (1.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 250 (0.40%)	3 / 132 (2.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 250 (0.40%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	GSK3511294	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	145 / 250 (58.00%)	78 / 132 (59.09%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	9 / 250 (3.60%)	7 / 132 (5.30%)	
occurrences (all)	10	7	
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 250 (4.80%)	10 / 132 (7.58%)	
occurrences (all)	17	13	
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 250 (0.80%)	4 / 132 (3.03%)	
occurrences (all)	3	4	
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	9 / 250 (3.60%) 23	6 / 132 (4.55%) 7	
Rhinitis allergic subjects affected / exposed occurrences (all)	11 / 250 (4.40%) 15	4 / 132 (3.03%) 4	
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	6 / 250 (2.40%) 6	7 / 132 (5.30%) 11	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	51 / 250 (20.40%) 51	27 / 132 (20.45%) 30	
Bronchitis subjects affected / exposed occurrences (all)	12 / 250 (4.80%) 18	5 / 132 (3.79%) 5	
Nasopharyngitis subjects affected / exposed occurrences (all)	29 / 250 (11.60%) 37	25 / 132 (18.94%) 32	
Pharyngitis subjects affected / exposed occurrences (all)	8 / 250 (3.20%) 8	2 / 132 (1.52%) 2	
Rhinitis subjects affected / exposed occurrences (all)	15 / 250 (6.00%) 17	10 / 132 (7.58%) 16	
Sinusitis subjects affected / exposed occurrences (all)	11 / 250 (4.40%) 14	6 / 132 (4.55%) 6	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	25 / 250 (10.00%) 39	14 / 132 (10.61%) 22	
Lower respiratory tract infection subjects affected / exposed occurrences (all)	10 / 250 (4.00%) 10	5 / 132 (3.79%) 7	
Laryngitis			

subjects affected / exposed occurrences (all)	9 / 250 (3.60%) 9	4 / 132 (3.03%) 4	
Influenza subjects affected / exposed occurrences (all)	19 / 250 (7.60%) 21	2 / 132 (1.52%) 2	
Respiratory tract infection subjects affected / exposed occurrences (all)	8 / 250 (3.20%) 9	6 / 132 (4.55%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 August 2021	Amendment 1
08 April 2022	Amendment 2

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39248309>