Clinical trial results:
Mepolizumab Long-term Access Programme (LAP) for Subjects who Participated in Study MEA115921 (Placebo-controlled Study of Mepolizumab in the Treatment of Eosinophilic Granulomatosis with Polyangiitis in Subjects Receiving Standard-of-care Therapy)

Summary

EudraCT number	2014-003162-25
Trial protocol	DE GB BE
Global end of trial date	16 February 2023

Results information

Result version number	v1 (current)
This version publication date	06 March 2024
First version publication date	06 March 2024

Trial information

Trial identification

Sponsor protocol code	MEA116841

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03298061
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, 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	16 February 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 February 2023
Global end of trial reached?	Yes
Global end of trial date	16 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study was to provide a mechanism to supply mepolizumab on an individual subject basis to eligible subjects who previously participated in GSK-sponsored study MEA115921.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 April 2015
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	Belgium: 3
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Japan: 6
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	United States: 49
Worldwide total number of subjects	100
EEA total number of subjects	29

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)	87
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who participated in clinical study MEA115921 and required a dose of prednisolone (or equivalent) of >= 5 mg/day for adequate control of their EGPA were included in this study based on their eligibility. Eligible participants received SC administered mepolizumab at a dose of 300 mg SC every 4 weeks.

Pre-assignment

Screening details:

A total of 100 participants entered the study and received mepolizumab.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Mepolizumab 300 mg

Arm description:

Participants who participated in clinical study MEA115921, who required additional dose of >=5 milligrams per day (mg/day) prednisolone for adequate control of their Eosinophilic Granulomatosis with Polyangiitis (EGPA) received 300 milligrams (mg) mepolizumab subcutaneous (SC) injection every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Mepolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of Mepolizumab 300 mg every 4 weeks.

Number of subjects in period 1	Mepolizumab 300 mg
Started	100
Completed	73
Not completed	27
Adverse event, serious fatal	1
Physician decision	7
Consent withdrawn by subject	10
Adverse event, non-fatal	2
Lack of efficacy	6
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Mepolizumab 300 mg
Reporting group description:	
Participants who participated in clinical study MEA115921, who required additional dose of >=5 milligrams per day (mg/day) prednisolone for adequate control of their Eosinophilic Granulomatosis with Polyangiitis (EGPA) received 300 milligrams (mg) mepolizumab subcutaneous (SC) injection every 4 weeks.	

Reporting group values	Mepolizumab 300 mg	Total	
Number of subjects	100	100	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	87	87	
From 65-84 years	13	13	
85 years and over	0	0	
Sex: Female, Male			
Units: Participants			
Female	57	57	
Male	43	43	
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1	1	
ASIAN - JAPANESE HERITAGE	6	6	
ASIAN - SOUTH EAST ASIAN HERITAGE	2	2	
WHITE - ARABIC/NORTH AFRICAN HERITAGE	1	1	
WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	90	90	
Age, Continuous			
Units: YEARS			
arithmetic mean	49.6		
standard deviation	± 13.90	-	

End points

End points reporting groups

Reporting group title	Mepolizumab 300 mg

Reporting group description:

Participants who participated in clinical study MEA115921, who required additional dose of >=5 milligrams per day (mg/day) prednisolone for adequate control of their Eosinophilic Granulomatosis with Polyangiitis (EGPA) received 300 milligrams (mg) mepolizumab subcutaneous (SC) injection every 4 weeks.

Primary: Number of participants with adverse events (AEs) and serious adverse events (SAEs)

End point title	Number of participants with adverse events (AEs) and serious adverse events (SAEs)[1]

End point description:

An AE is any untoward medical occurrence in a participants, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires hospitalization or prolongation of existing hospitalization; results in disability/incapacity; is a congenital anomaly/birth defect; other important medical events based on medical or scientific judgment; and is associated with liver injury and impaired liver function. Additionally, systemic (that is, allergic/hypersensitivity and non-allergic) reactions and local injection site reactions were recorded throughout the treatment and follow- up period. Safety Population consisted of participants who received at least one dose of study drug.

End point type	Primary

End point timeframe:

Up to 89 Months

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: This endpoint was descriptive, hence no statistical analysis to report.

End point values	Mepolizumab 300 mg			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: Participants				
AE	98			
SAE	38			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 89 Months

Adverse event reporting additional description:

Adverse events (AEs) and Serious adverse event (SAEs) were collected for all participants within the safety population which comprised of all participants who received at least one dose of open-label mepolizumab.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Mepolizumab 300 mg

Reporting group description:

Participants who participated in clinical study MEA115921, who required additional dose of >=5 milligrams per day (mg/day) prednisolone for adequate control of their Eosinophilic Granulomatosis with Polyangiitis (EGPA) received 300 milligrams (mg) mepolizumab subcutaneous (SC) injection every 4 weeks.

Serious adverse events	Mepolizumab 300 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	38 / 100 (38.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Vasculitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Eosinophilic granulomatosis with polyangiitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Salpingitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Heavy menstrual bleeding			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Vocal cord dysfunction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Respiratory failure				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Dyspnoea				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Asthma				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	6 / 100 (6.00%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Stress				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Post procedural fever				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal injury				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
alternative dictionary used: MedDRA v25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Atrial fibrillation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cervical cord compression				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal ulcer				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal prolapse				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal incontinence				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin ulcer				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dermal cyst				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Nephrolithiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Renal colic				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ureterolithiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back pain				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
COVID-19				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bursitis infective			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis E			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronavirus infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gastroenteritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia staphylococcal				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia pneumococcal				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Influenza				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 100 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 100 (1.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hyperglycaemia				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Mepolizumab 300 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	97 / 100 (97.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
General disorders and administration site conditions			
Oedema peripheral			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Injection site reaction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	29		
Injection site haematoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	5		
Influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Fatigue			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	10 / 100 (10.00%)		
occurrences (all)	12		
Asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	14		
Immune system disorders			
Eosinophilic granulomatosis with polyangiitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	26 / 100 (26.00%)		
occurrences (all)	87		
Cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	10		
Dyspnoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	10		
Epistaxis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	5		
Nasal congestion			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Nasal polyps			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Sinus congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	9		
Wheezing			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Psychiatric disorders			
Depression			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	6		
Insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	8		
Investigations			
Weight decreased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Injury, poisoning and procedural complications			

Arthropod bite				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	5 / 100 (5.00%)			
occurrences (all)	5			
Bone contusion				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	3			
Contusion				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	5 / 100 (5.00%)			
occurrences (all)	5			
Fall				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	8 / 100 (8.00%)			
occurrences (all)	10			
Foot fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	5 / 100 (5.00%)			
occurrences (all)	7			
Hand fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	3			
Ligament sprain				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	3			
Muscle strain				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 100 (4.00%)			
occurrences (all)	6			
Rib fracture				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	6		
Nervous system disorders			
Dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	8		
Headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	14 / 100 (14.00%)		
occurrences (all)	42		
Hypoaesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Migraine			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	8		
Sciatica			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	6		
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	5		
Eye disorders			
Cataract			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Gastrointestinal disorders			
Vomiting			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	10 / 100 (10.00%)		
occurrences (all)	10		
Nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	14 / 100 (14.00%)		
occurrences (all)	18		
Gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	5		
Diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	14 / 100 (14.00%)		
occurrences (all)	16		
Abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	26		
Abdominal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Abdominal distension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Erythema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	17		
Rash			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	15 / 100 (15.00%)		
occurrences (all)	22		
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	20 / 100 (20.00%)		
occurrences (all)	29		
Arthritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	16 / 100 (16.00%)		
occurrences (all)	19		
Bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	6		
Myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	18		
Neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Pain in extremity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	10 / 100 (10.00%)		
occurrences (all)	13		
Infections and infestations			
Nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	33 / 100 (33.00%)		
occurrences (all)	113		
Lower respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	21		
Influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	10 / 100 (10.00%)		
occurrences (all)	12		
Herpes simplex			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	4 / 100 (4.00%)			
occurrences (all)	4			
Gastroenteritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	8 / 100 (8.00%)			
occurrences (all)	11			
Ear infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	8 / 100 (8.00%)			
occurrences (all)	9			
Oral candidiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	5 / 100 (5.00%)			
occurrences (all)	5			
Conjunctivitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	4			
COVID-19				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	6 / 100 (6.00%)			
occurrences (all)	7			
Bronchitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	29 / 100 (29.00%)			
occurrences (all)	47			
Acute sinusitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	8 / 100 (8.00%)			
occurrences (all)	14			
Cystitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	4			

Otitis media				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 100 (4.00%)			
occurrences (all)	9			
Pharyngitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 100 (4.00%)			
occurrences (all)	4			
Pneumonia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	3			
Pulpitis dental				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	5			
Respiratory tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	13 / 100 (13.00%)			
occurrences (all)	15			
Rhinitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	6			
Sinusitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	30 / 100 (30.00%)			
occurrences (all)	52			
Tooth abscess				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 100 (3.00%)			
occurrences (all)	3			
Upper respiratory tract infection				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	31 / 100 (31.00%)		
occurrences (all)	43		
Urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	16		
Viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	8		
Viral upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	8		
Metabolism and nutrition disorders			
Vitamin D deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 February 2015	Country-specific amendment for the UK: clarification regarding the estimated study end date for the UK and clarification regarding definition of abstinence as acceptable method of birth control.
12 March 2015	Country-specific amendment for the UK: Further clarification regarding the estimated study end date for the UK.
20 August 2015	Amendment to indicate that use of other biological agents will be permitted on agreement with the GSK Medical Monitor. Additional administrative updates.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported