



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
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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
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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
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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]
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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
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Mepolizumab 300 mg
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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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 1 0 / 0			
Respiratory distress alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 1 0 / 0			
Pneumothorax alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 1 0 / 0			
Hypoxia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 1 0 / 1			
Dyspnoea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 2 0 / 1			
Chronic obstructive pulmonary disease alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 100 (1.00%) 0 / 4 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			

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

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasal polyps</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Sinus congestion</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Wheezing</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 100 (3.00%)</p> <p>3</p> <p>6 / 100 (6.00%)</p> <p>8</p> <p>6 / 100 (6.00%)</p> <p>8</p> <p>4 / 100 (4.00%)</p> <p>9</p> <p>3 / 100 (3.00%)</p> <p>3</p>		
<p>Psychiatric disorders</p> <p>Depression</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Insomnia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>6 / 100 (6.00%)</p> <p>6</p> <p>7 / 100 (7.00%)</p> <p>8</p>		
<p>Investigations</p> <p>Weight decreased</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>5 / 100 (5.00%)</p> <p>5</p>		
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 occurrences (all)	6 / 100 (6.00%) 6		
Nervous system disorders Dizziness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) Headache alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) Hypoaesthesia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) Migraine alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) Paraesthesia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) Sciatica alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	8 / 100 (8.00%) 8 14 / 100 (14.00%) 42 3 / 100 (3.00%) 3 3 / 100 (3.00%) 3 8 / 100 (8.00%) 8 4 / 100 (4.00%) 6		
Blood and lymphatic system disorders Anaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	4 / 100 (4.00%) 5		
Eye disorders Cataract alternative dictionary used: MedDRA 25.1			

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

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

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

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