Clinical trial results:
A Randomized, Double-Blind, Parallel Group, Multicenter, Phase 3 Study to Compare the Efficacy and Safety of Bmab 1200 and Stelara® in Patients with Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2021-006668-25
Trial protocol	EE LV
Global end of trial date	15 November 2023

Results information

Result version number	v1 (current)
This version publication date	17 August 2025
First version publication date	17 August 2025

Trial information

Trial identification

Sponsor protocol code	BM12H-PSO-03-G-02

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05335356
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 153118

Notes:

Sponsors

Sponsor organisation name	Biocon Biologics UK Limited
Sponsor organisation address	16 Great Queen Street, Covent Garden, London, United Kingdom, WC2B 5AH, London, United Kingdom, WC2B 5AH
Public contact	Clinical Development, Biocon Biologics Limited, +91 80 6775 1323, subramanian.l101@biocon.com
Scientific contact	Clinical Development, Biocon Biologics Limited, +91 80 6775 1323, subramanian.l101@biocon.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	12 September 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate equivalent efficacy between Bmab 1200 and Stelara® in patients with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Ethics committee approval was obtained prior to trial initiation. All participants provided written informed consent. Confidentiality was maintained through coded identifiers and secure data systems. Adverse events were monitored continuously

Background therapy:

Concomitant medications/procedures were those where the medication/procedure started after the date of the first dose of study drug, or where the medication/procedure started before the first dose of study drug and continued after the first dose of study drug until anytime up to the Week 52 visit.
Concomitance was assessed for TP1 on the FAS, TP2 on the FAS2, and TP2 plus TP3 on the FAS3. Thus, a medication/procedure may have been concomitant over TP1 and TP2,
TP2 and TP3, or TP1, TP2, and TP3 if it occurred during multiple treatment periods.

Evidence for comparator:

Psoriasis was selected for this Phase 3 study as Stelara® is used as monotherapy in this indication, allowing a clearer demonstration of biosimilarity compared to conditions like psoriatic arthritis, Crohn's disease, or ulcerative colitis, where concomitant immunosuppressants are common. Psoriasis also shows a strong treatment effect and notable immunogenicity in Stelara® studies, aiding in detecting differences between Bmab 1200 and Stelara®.
To ensure balanced treatment arms across countries, patients will be stratified by region. Body weight (≤100 kg or >100 kg) will determine dosing (45 mg or 90 mg) and is a stratification factor to maintain dose balance. Additional stratification includes prior biologic therapy exposure (Yes/No) and presence of psoriatic arthritis (Yes/No), as both may influence treatment response.
A single switch via rerandomization at Week 16 is included to assess immunogenicity and safety after transitioning from Stelara® to Bmab 1200 using descriptive statistics.

Actual start date of recruitment	29 April 2022
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	European Union: 378
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	384
EEA total number of subjects	0

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)	354
From 65 to 84 years	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in Europe and North America and enrolled patients across 41 sites in 5 countries.

Pre-assignment

Screening details:

A suitable number of patients were to be screened to enroll a total of 384 patients with moderate to severe chronic plaque psoriasis who were deemed eligible for receiving systemic therapy or phototherapy and were naïve to ustekinumab.

Period 1

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

Blinding implementation details:

The study was double-blind, with treatment assignments concealed from patients and investigators. Randomization and drug dispensing were managed by unblinded staff using standardized secondary packaging. Unblinding occurred only in emergencies or for regulatory reasons. Two database locks were set at Week 28 and Week 52, with separate teams handling analyses to maintain blinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Bmab 1200

Arm description:

Bmab 1200 45 mg Bmab1200 90 mg
Bmab1200: 45 mg , 90mg at Week 0, 4, 16, 28and 40

Arm type	Experimental
Investigational medicinal product name	Bmab1200
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Bmab1200:- 45 mg , 90 mg at Week 0, 4, 16, 28 and 40.

Arm title	Stelara

Arm description:

Stelara: 45 mg , 90 mg at Week0, 4, 16, 28 and 40; Beforedosing at Week 16, patients inthe Stelara group wererandomly assigned in a 1:1 ratioto receive either Bmab 1200 orStelara

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

Dosage and administration details:

Stelara: 45 mg , 90 mg at Week0, 4, 16, 28 and 40; Beforedosing at Week 16, patients inthe Stelara group wererandomly assigned in a 1:1 ratioto receive either Bmab 1200 orStelara

Number of subjects in period 1	Bmab 1200	Stelara
Started	191	193
Completed	163	161
Not completed	28	32
Consent withdrawn by subject	6	6
Physician decision	4	7
Other	16	16
Lost to follow-up	1	1
Patient does not achieve at least PASI 75 response	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial
Reporting group description: -	

Reporting group values	Overall Trial	Total	
Number of subjects	384	384	
Age categorical Units: Subjects			
Adults (18-64 years)	354	354	
From 65-84 years	30	30	
Age continuous Units: years			
arithmetic mean	43.2		
standard deviation	± 13.34	-	
Gender categorical Units: Subjects			
Female	127	127	
Male	257	257	

Subject analysis sets	
Subject analysis set title	Bmab1200
Subject analysis set type	Full analysis
Subject analysis set description: Full Analysis Set	
Subject analysis set title	Stelara
Subject analysis set type	Full analysis
Subject analysis set description: Full Analysis Set	

Reporting group values	Bmab1200	Stelara	
Number of subjects	191	193	
Age categorical Units: Subjects			
Adults (18-64 years)	178	176	
From 65-84 years	13	17	
Age continuous Units: years			
arithmetic mean	42.5	43.9	
standard deviation	± 13.09	± 13.58	
Gender categorical Units: Subjects			
Female	70	57	
Male	121	136	

End points

End points reporting groups

Reporting group title	Bmab 1200
Reporting group description:	
Bmab 1200 45 mg Bmab1200 90 mg Bmab1200: 45 mg , 90mg at Week 0, 4, 16, 28and 40	
Reporting group title	Stelara
Reporting group description:	
Stelara: 45 mg , 90 mg at Week0, 4, 16, 28 and 40; Beforedosing at Week 16, patients inthe Stelara group wererandomly assigned in a 1:1 ratioto receive either Bmab 1200 orStelara	
Subject analysis set title	Bmab1200
Subject analysis set type	Full analysis
Subject analysis set description:	
Full Analysis Set	
Subject analysis set title	Stelara
Subject analysis set type	Full analysis
Subject analysis set description:	
Full Analysis Set	

Primary: Psoriasis Area and Severity Index (PASI)

End point title	Psoriasis Area and Severity Index (PASI)
End point description:	
Percentage change from baseline in the Psoriasis Area and Severity Index score at Week12	
End point type	Primary
End point timeframe:	
Baseline to Week 12	

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	191	193		
Units: Percentage change from baseline				
least squares mean (standard error)	-79.87 (± 2.818)	-80.55 (± 2.783)		

Statistical analyses

Statistical analysis title	Analysis of the Primary Estimand
Statistical analysis description:	
ANCOVA will assess percentage change in PASI score at Week 12 on the FAS, using imputed datasets. The model includes baseline stratification factors as fixed effects. Treatment differences, estimated via least squares means and restricted maximum likelihood, will be pooled using Rubin’s rule with 90% and 95% confidence intervals	
Comparison groups	Bmab1200 v Stelara

Number of subjects included in analysis	384
Analysis specification	Pre-specified
Analysis type	equivalence
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.68
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.27
upper limit	2.63
Variability estimate	Standard error of the mean

Secondary: PASI Score

End point title	PASI Score
End point description:	
Percentage change from baseline in the PASI score at Baseline through Week 28 and 52	
End point type	Secondary
End point timeframe:	
Baseline through Week 28	

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	168	81		
Units: Percentage change from Baseline				
arithmetic mean (standard deviation)	-95.50 (± 6.068)	-96.01 (± 6.461)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Improvement

End point title	PASI Improvement
End point description:	
PASI improvement of ≥50% relative to baseline (PASI 50), PASI improvement of ≥75%relative to baseline (PASI 75), and PASI improvement of ≥90% relative to Baseline throughWeek 28 and 52	
End point type	Secondary
End point timeframe:	
Baseline through Week 28	

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	168	80		
Units: participants				
PASI 50	168	80		
PASI 75	168	79		
PASI 90	140	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Static Physician’s Global Assessment (sPGA)

End point title	Static Physician’s Global Assessment (sPGA)

End point description:

Static Physician's Global Assessment (sPGA) response of cleared or almost clear/minimal(PGA of 0 or 1) at Weeks 4, 8, 12, 16, 20, 28, and 52

End point type	Secondary

End point timeframe:

Baseline through Week 28

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	168	81		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-3.0 (± 1.21)	-2.9 (± 1.21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Affected Body Surface Area

End point title	Affected Body Surface Area

End point description:

Change from baseline in affected body surface area at Weeks 4, 8, 12, 16, 20, 28 and 52

End point type	Secondary

End point timeframe:

Baseline through Week 28

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	168	81		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-26.52 (± 15.152)	-25.91 (± 13.323)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dermatology Life Quality Index Scores

End point title	Dermatology Life Quality Index Scores
End point description:	
Change from baseline in quality of life as measured by Dermatology Life Quality Index scores at Weeks 4, 8, 12, 16, 20, 28 and 52	
End point type	Secondary
End point timeframe:	
Baseline through Week 28	

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	170	90		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-12.2 (± 6.84)	-10.5 (± 6.74)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dermatology Life Quality Index Scores

End point title	Dermatology Life Quality Index Scores
End point description:	
Change from baseline in quality of life as measured by Dermatology Life Quality Indexscores at Weeks 4, 8, 12, 16, 20, 28 and 52	
End point type	Secondary
End point timeframe:	
Baseline through Week 52	

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	152	79		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-12.8 (± 6.73)	-11.5 (± 6.35)		

Statistical analyses

No statistical analyses for this end point

Secondary: Static Physician’s Global Assessment (sPGA)

End point title	Static Physician’s Global Assessment (sPGA)

End point description:

Static Physician's Global Assessment (sPGA) response of cleared or almost clear/minimal(PGA of 0 or 1) at Weeks 4, 8, 12, 16, 20, 28, and 52

End point type	Secondary

End point timeframe:

Baseline through Week 52

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	163	80		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-3.1 (± 1.21)	-3.0 (± 1.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Affected Body Surface Area

End point title	Affected Body Surface Area

End point description:

Change from baseline in affected body surface area at Weeks 4, 8, 12, 16, 20, 28 and 52

End point type	Secondary

End point timeframe:

Baseline through Week 52

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	163	80		
Units: Change from Baseline				
arithmetic mean (standard deviation)	-27.42 (± 15.119)	-26.50 (± 13.160)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Improvement

End point title	PASI Improvement

End point description:

PASI improvement of ≥50% relative to baseline (PASI 50), PASI improvement of ≥75%relative to baseline (PASI 75), and PASI improvement of ≥90% relative to Baseline through Week 28 and 52

End point type	Secondary

End point timeframe:

Baseline through week 52

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	163	80		
Units: Participants				
PASI 50	163	80		
PASI 75	159	80		
PASI 90	133	70		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score

End point title	PASI Score

End point description:

Percentage change from baseline in the PASI score at Baseline through Week 28 and 52

End point type	Secondary

End point timeframe:

Baseline through Week 52

End point values	Bmab1200	Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	163	81		
Units: Percentage change from Baseline				
arithmetic mean (standard deviation)	-95.50 (± 7.507)	-96.60 (± 5.671)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Safety:-TEAEs Including Adverse Events of Special Interest and Adverse Reactions During the Treatment Period

End point title	Safety:-TEAEs Including Adverse Events of Special Interest and Adverse Reactions During the Treatment Period

End point description:

Safety:-Treatment-emergent Adverse Events, Including Adverse Events of Special Interest and Adverse Reactions During the Treatment Period

End point type	Other pre-specified

End point timeframe:

Baseline to Week 52

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: Participants				
Endometrial adenocarcinoma	1			
Squamous cell carcinoma of the tongue	1			
Angioedema	0			
Rash maculo-papular	0			
Abdominal pain	1			
Jaundice cholestatic	1			
Alcohol poisoning	0			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Safety:- Injection-site Reactions

End point title	Safety:- Injection-site Reactions

End point description:

Injection-site reactions at Day 1, Week 4, Week 16, and throughout the study

End point type	Other pre-specified

End point timeframe:
Baseline through Week 28 and 52

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Safety:- Hypersensitivity

End point title	Safety:- Hypersensitivity

End point description:
Hypersensitivity at Day 1, Week 4, Week 16, and throughout the study

End point type	Other pre-specified

End point timeframe:
Baseline through Week 28 and 52

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed	191			
Units: Participants	1			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Immunogenicity:-Developing Antidrug Antibodies

End point title	Immunogenicity:-Developing Antidrug Antibodies

End point description:
Proportion of patients developing antidrug antibodies

End point type	Other pre-specified

End point timeframe:
Baseline through Week 28

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed	185			
Units: Participants				
ADA positive	129			
ADA negative	53			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Immunogenicity:-Developing Antidrug Antibodies

End point title	Immunogenicity:-Developing Antidrug Antibodies
End point description: Proportion of patients developing antidrug antibodies	
End point type	Other pre-specified
End point timeframe: Postdosing on Week 28 through Week 52	

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed	168			
Units: Participants				
ADA positive	107			
ADA negative	56			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Developing Neutralizing Antibodies

End point title	Developing Neutralizing Antibodies
End point description: Proportion of patients with neutralizing antibodies	
End point type	Other pre-specified
End point timeframe: Baseline through Week 28	

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed	185			
Units: Participants				
Nab reactive	18			
Nab negative	111			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Developing Neutralizing Antibodies

End point title	Developing Neutralizing Antibodies
End point description: Proportion of patients neutralizing antibodies	
End point type	Other pre-specified
End point timeframe: Postdosing on Week 28 through Week 52	

End point values	Bmab1200			
Subject group type	Subject analysis set			
Number of subjects analysed	168			
Units: Participants				
Nab reactive	17			
Nab negative	90			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Pharmacokinetic:-Serum Concentrations

End point title	Pharmacokinetic:-Serum Concentrations
End point description: Serum concentrations of ustekinumab	
End point type	Other pre-specified
End point timeframe: Postdosing on Week 28	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Pharmacokinetic:-Serum Concentrations

End point title	Pharmacokinetic:-Serum Concentrations
End point description: Serum concentrations of Ustekinumab	
End point type	Other pre-specified
End point timeframe: Postdosing on Week 52	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Treatment-Emergent Adverse Events (TEAEs) During TP1 and Through the Study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	Bmab1200
Reporting group description: Bmab 1200 45 mg Bmab 1200 90 mg Bmab1200: 45 mg , 90 mg at Week 0, 4, 16, 28 and 40	
Reporting group title	Stelara
Reporting group description: Stelara 45 mg Stelara 90 mg Stelara: 45 mg , 90 mg at Week 0, 4, 16, 28 and 40; Before dosing at Week 16, patients in the Stelara group were randomly assigned in a 1:1 ratio to receive either Bmab 1200 or Stelara	
Reporting group title	Stelara-Bmab1200
Reporting group description: Bmab 1200 45 mg 90 mg Stelara 45 mg 90 mg Subject who received Stelara 45 mg dose have received Bmab 1200 dose 45 mg Subject who received Stelara 90 mg dose have received Bmab 1200 dose 90 mg	

Serious adverse events	Bmab1200	Stelara	Stelara-Bmab1200
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 191 (3.14%)	0 / 101 (0.00%)	1 / 92 (1.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute myocardial infarction			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterovaginal prolapse			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Bmab1200	Stelara	Stelara-Bmab1200
Total subjects affected by non-serious adverse events			
subjects affected / exposed	111 / 191 (58.12%)	48 / 101 (47.52%)	51 / 92 (55.43%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Haemangioma			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Meningioma			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	3 / 191 (1.57%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	3	1	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Genital haemorrhage			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Heavy menstrual bleeding			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Menstruation irregular			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Prostatitis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Uterovaginal prolapse			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Anxiety disorder			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Illness anxiety disorder			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine amino transferase increased			
subjects affected / exposed	12 / 191 (6.28%)	6 / 101 (5.94%)	2 / 92 (2.17%)
occurrences (all)	14	9	3
Aspartate amino transferase increased			
subjects affected / exposed	7 / 191 (3.66%)	2 / 101 (1.98%)	0 / 92 (0.00%)
occurrences (all)	7	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased †			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Blood cholesterol increased			
subjects affected / exposed	4 / 191 (2.09%)	2 / 101 (1.98%)	2 / 92 (2.17%)
occurrences (all)	6	3	2
Blood glucose abnormal			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	2 / 191 (1.05%)	3 / 101 (2.97%)	1 / 92 (1.09%)
occurrences (all)	3	3	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Blood phosphorus decreased			

subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	3 / 191 (1.57%)	2 / 101 (1.98%)	2 / 92 (2.17%)
occurrences (all)	3	2	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Blood triglycerides increased			
subjects affected / exposed	11 / 191 (5.76%)	3 / 101 (2.97%)	3 / 92 (3.26%)
occurrences (all)	13	4	5
C-reactive protein increased			
subjects affected / exposed	0 / 191 (0.00%)	2 / 101 (1.98%)	2 / 92 (2.17%)
occurrences (all)	0	2	2
Creatinine renal clearance decreased			
subjects affected / exposed	2 / 191 (1.05%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	2	1	0
Gamma-glutamy ltransferase increased			
subjects affected / exposed	6 / 191 (3.14%)	2 / 101 (1.98%)	1 / 92 (1.09%)
occurrences (all)	7	2	1
Glucose urine present			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Haemoglobin increased			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
High density lipoprotein decreased			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Lipids increased			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	1	1	2
Monocyte count increased			

subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	3 / 191 (1.57%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	3	0	1
White blood cells urine positive			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Fibula fracture			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Fractured coccyx			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Post-traumatic neck syndrome			

subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Tendon rupture			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Angina pectoris			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Bundle branch block right			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Cardiac discomfort			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Left atrial enlargement			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			

subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 191 (1.57%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	4	0	0
Headache			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	2	2	1
Ischaemic stroke			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	2 / 191 (1.05%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	2	1	0
Depressed mood			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 191 (2.09%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	4	0	0
Eosinophilia			

subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	1	1	1
Erythropenia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	1	1	1
Leukopenia			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	4 / 191 (2.09%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	4	0	0
Secondary thrombocytosis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Thrombocytosis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane perforation			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			

subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 191 (1.05%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Food poisoning			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Cholecystitis acute			

subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Cholestasis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Jaundice cholestatic			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Angioedema			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	2 / 191 (1.05%)	2 / 101 (1.98%)	1 / 92 (1.09%)
occurrences (all)	2	2	1
Psoriasis			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	2 / 92 (2.17%)
occurrences (all)	2	0	2
Rash maculo-papular			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0

Sensitive skin			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Urticaria			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	2	0	1
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	0	1	1
Hyperoxaluria			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Ketonuria			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Leukocyturia			
subjects affected / exposed	3 / 191 (1.57%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	3	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	4 / 191 (2.09%)	1 / 101 (0.99%)	3 / 92 (3.26%)
occurrences (all)	4	1	3
Renal impairment			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 191 (1.05%)	3 / 101 (2.97%)	0 / 92 (0.00%)
occurrences (all)	2	4	0
Joint contracture			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Psoriatic arthropathy			
subjects affected / exposed	3 / 191 (1.57%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	3	2	0
Spinal osteoarthritis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Bacteriuria			

subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	3 / 191 (1.57%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	3	0	0
COVID-19			
subjects affected / exposed	4 / 191 (2.09%)	0 / 101 (0.00%)	3 / 92 (3.26%)
occurrences (all)	4	0	3
Conjunctivitis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	2 / 92 (2.17%)
occurrences (all)	1	0	2
Folliculitis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	1	0	1
Fungal skin infection			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Giardiasis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Influenza			

subjects affected / exposed	4 / 191 (2.09%)	5 / 101 (4.95%)	5 / 92 (5.43%)
occurrences (all)	4	8	5
Nasopharyngitis			
subjects affected / exposed	18 / 191 (9.42%)	6 / 101 (5.94%)	8 / 92 (8.70%)
occurrences (all)	23	6	8
Onychomycosis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 191 (0.52%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	1 / 191 (0.52%)	2 / 101 (1.98%)	1 / 92 (1.09%)
occurrences (all)	1	2	1
Otitis externa			
subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	4 / 191 (2.09%)	1 / 101 (0.99%)	2 / 92 (2.17%)
occurrences (all)	5	1	2
Pharyngitis streptococcal			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 191 (0.00%)	2 / 101 (1.98%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection viral			

subjects affected / exposed	0 / 191 (0.00%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	0	1	2
Rhinitis			
subjects affected / exposed	2 / 191 (1.05%)	2 / 101 (1.98%)	3 / 92 (3.26%)
occurrences (all)	3	3	3
Sinusitis			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Sinusitis bacterial			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Tongue fungal infection			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	2 / 191 (1.05%)	1 / 101 (0.99%)	1 / 92 (1.09%)
occurrences (all)	2	1	2
Tonsillitis bacterial			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Tooth abscess			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	6 / 191 (3.14%)	1 / 101 (0.99%)	6 / 92 (6.52%)
occurrences (all)	7	1	7
Urethritis			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	6 / 191 (3.14%)	2 / 101 (1.98%)	3 / 92 (3.26%)
occurrences (all)	6	2	3
Urinary tract infection fungal			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			

subjects affected / exposed	3 / 191 (1.57%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	3	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	2	0	2
Bone contusion			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Acquired mixed hyperlipidaemia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
Glucose tolerance impaired			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	4 / 191 (2.09%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	4	0	0
Hyperlipidaemia			
subjects affected / exposed	5 / 191 (2.62%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	5	0	0
Hypertriglyceridaemia			
subjects affected / exposed	6 / 191 (3.14%)	1 / 101 (0.99%)	0 / 92 (0.00%)
occurrences (all)	8	1	0
Hyperuricaemia			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Latent autoimmune diabetes in adults			

subjects affected / exposed	0 / 191 (0.00%)	0 / 101 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Metabolic syndrome			
subjects affected / exposed	1 / 191 (0.52%)	0 / 101 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Obesity			
subjects affected / exposed	0 / 191 (0.00%)	2 / 101 (1.98%)	1 / 92 (1.09%)
occurrences (all)	0	2	1
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 191 (1.05%)	0 / 101 (0.00%)	2 / 92 (2.17%)
occurrences (all)	2	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported