Clinical trial results:
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Two Arm, Phase 2 Clinical Trial to Evaluate the Efficacy and Safety of LY3361237 to Treat Adults with At Least Moderately Active Systemic Lupus Erythematosus

Summary

EudraCT number	2021-001406-30
Trial protocol	PL
Global end of trial date	29 December 2023

Results information

Result version number	v1 (current)
This version publication date	03 January 2025
First version publication date	03 January 2025

Trial information

Trial identification

Sponsor protocol code	J1V-MC-BT01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05123586
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, United States, 46825
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	29 December 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 December 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of 450 mg LY3361237 every 2 weeks versus placebo with respect to arthritis and/or rash remission in participants with Systemic Lupus Erythematosus (SLE)
The main purpose of this study is to assess the efficacy and safety of LY3361237 in participants with at least moderately active systemic lupus erythematosus (SLE). Study will last up to 34 weeks and may include up to 15 visits.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 March 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	Poland: 13
Country: Number of subjects enrolled	Argentina: 15
Country: Number of subjects enrolled	United States: 37
Country: Number of subjects enrolled	Taiwan: 5
Country: Number of subjects enrolled	Mexico: 15
Worldwide total number of subjects	85
EEA total number of subjects	13

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)	84
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Not applicable

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	450 Milligrams (mg) - LY3361237

Arm description:

Participants received 450 mg of LY3361237 administered subcutaneously (SC) every 2 weeks (Q2W) along with their usual Standard of Care (SOC) medication for 24 weeks

Arm type	Experimental
Investigational medicinal product name	LY3361237
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously.

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

Dosage and administration details:

Administered subcutaneously.

Arm title	Placebo

Arm description:

Participants received placebo administered SC Q2W along with their usual SOC medication for 24 weeks.

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

Dosage and administration details:

Administered subcutaneously

Number of subjects in period 1	450 Milligrams (mg) - LY3361237	Placebo
Started	42	43
Received At Least One Dose of Study Drug	42	43
Completed	41	39
Not completed	1	4
Physician decision	1	1
Consent withdrawn by subject	-	3

Baseline characteristics

Reporting groups	
Reporting group title	450 Milligrams (mg) - LY3361237
Reporting group description:	
Participants received 450 mg of LY3361237 administered subcutaneously (SC) every 2 weeks (Q2W) along with their usual Standard of Care (SOC) medication for 24 weeks	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered SC Q2W along with their usual SOC medication for 24 weeks.	

Reporting group values	450 Milligrams (mg) - LY3361237	Placebo	Total
Number of subjects	42	43	85
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	41	43	84
From 65-84 years	1	0	1
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	38	42	80
Male	4	1	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	25	27	52
Not Hispanic or Latino	17	15	32
Unknown or Not Reported	0	1	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	7	7	14
Asian	3	3	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	3	4
White	30	30	60
More than one race	1	0	1
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Argentina	7	8	15
United States	18	19	37
Taiwan	3	2	5

Poland	6	7	13
Mexico	8	7	15

End points

End points reporting groups

Reporting group title	450 Milligrams (mg) - LY3361237
Reporting group description:	
Participants received 450 mg of LY3361237 administered subcutaneously (SC) every 2 weeks (Q2W) along with their usual Standard of Care (SOC) medication for 24 weeks	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered SC Q2W along with their usual SOC medication for 24 weeks.	

Primary: Percentage of Participants With Arthritis and/or Rash at Baseline Who Achieve Remission of Arthritis and/or Rash

End point title	Percentage of Participants With Arthritis and/or Rash at Baseline Who Achieve Remission of Arthritis and/or Rash[1]
End point description:	
Remission of arthritis and/or rash is defined by the following: if only arthritis is present at baseline, then the primary endpoint is met if arthritis is absent at Week 24; if only rash is present at baseline, then the primary endpoint is met if rash is absent at Week 24; if both arthritis and rash are present at baseline, then the primary endpoint is met if either arthritis, or rash, or both arthritis and rash are absent at Week 24. Analysis Population Description (APD): All participants who received at least 1 dose of study drug and had evaluable data for this outcome.	
End point type	Primary
End point timeframe:	
Week 24	
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: No inferential statistics was planned for this end point.	

End point values	450 Milligrams (mg) - LY3361237	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	43		
Units: Percentage of participants				
number (not applicable)	11.9	20.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieve Systemic Lupus Erythematosus Disease Activity Index-4 (SLEDAI-4) Response

End point title	Percentage of Participants Who Achieve Systemic Lupus Erythematosus Disease Activity Index-4 (SLEDAI-4) Response
End point description:	
Percentage of participants who achieved SLEDAI-4 response was assessed. A SLEDAI-4 response is	

defined as a ≥ 4-point reduction in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score from baseline. The SLEDAI-2K score range is from a minimum of 0 to a maximum of 105 (higher scores represent higher disease activity).

APD: All participants who received at least 1 dose of the study drug and had evaluable data for this outcome.

End point type	Secondary

End point timeframe:

Week 24

End point values	450 Milligrams (mg) - LY3361237	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	43		
Units: percentage of participants				
number (not applicable)	9.5	16.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieve Systemic Lupus Erythematosus Responder Index-4 (SRI-4 Response)

End point title	Percentage of Participants Who Achieve Systemic Lupus Erythematosus Responder Index-4 (SRI-4 Response)

End point description:

Percentage of participants who achieved SRI-4 response was assessed. SRI-4 measures reduction in SLE disease activity and is a composite measure that includes the SLE Disease Activity Index (SLEDAI-2K), British Isles Lupus Activity Group (BILAG) 2004 and Physician Global Assessment. It is defined as: 1) Reduction of ≥4 points from baseline in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score; 2) no new British Isles Lupus Assessment Group (BILAG) A and no more than 1 new BILAG B disease activity scores and 3) no worsening (defined as an increase of 0.3 points [10 mm] from baseline) in the Physician's Global Assessment of Disease Activity. The score range is from 0 to 100, with higher scores indicating greater disease activity.

APD: All participants who received at least 1 dose of study drug and have evaluable data for this outcome.

End point type	Secondary

End point timeframe:

Week 24

End point values	450 Milligrams (mg) - LY3361237	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	43		
Units: Percentage of participants				
number (not applicable)	9.5	16.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Steady-state Trough Serum Concentration of LY3361237 at Week 24

End point title	Pharmacokinetics (PK): Steady-state Trough Serum Concentration of LY3361237 at Week 24[2]

End point description:

PK: Steady-state trough serum concentration of LY3361237 at Week 24 was assessed.

APD: All participants who received at least one dose of LY3361237 and had evaluable PK data for this outcome.

End point type	Secondary

End point timeframe:

Week 24

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	450 Milligrams (mg) - LY3361237			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: micrograms per milliliter (µg/mL)				
arithmetic mean (standard deviation)	144 (± 73.8)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 25 Weeks

Adverse event reporting additional description:

All participants who received at least 1 dose of study drug. Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	450 mg - LY3361237

Reporting group description:

Participants received 450 mg of LY3361237 administered SC Q2W along with their usual SOC medication for 24 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received placebo administered SC Q2W along with their usual SOC medication for 24 weeks.

Serious adverse events	450 mg - LY3361237	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 42 (11.90%)	1 / 43 (2.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Investigations			
blood glucose abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
joint dislocation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
diplopia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
volvulus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
systemic lupus erythematosus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	450 mg - LY3361237	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 42 (66.67%)	27 / 43 (62.79%)	
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			

hysterectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[1]	0 / 38 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
wisdom teeth removal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	2	
fatigue			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 42 (7.14%)	0 / 43 (0.00%)	
occurrences (all)	3	0	
injection site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	21	0	
injection site pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	6 / 42 (14.29%)	3 / 43 (6.98%)	
occurrences (all)	97	32	
injection site oedema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
injection site bruising			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	6	0	
injection site erythema			
alternative dictionary used:			

MedDRA 26.1			
subjects affected / exposed	5 / 42 (11.90%)	1 / 43 (2.33%)	
occurrences (all)	14	1	
injection site haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
atrophic vulvovaginitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[2]	1 / 38 (2.63%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
catarrh			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
cough			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	2 / 43 (4.65%)	
occurrences (all)	1	2	
dysphonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
epistaxis			

alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	1 / 43 (2.33%)	
occurrences (all)	1	1	
rhinitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	1 / 43 (2.33%)	
occurrences (all)	1	1	
sinus congestion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
wheezing			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
insomnia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	2	0	
Investigations			
amylase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
blood pressure increased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
cardiolipin antibody positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
brachial plexus injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
fall			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
foot fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
head injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
joint injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
thermal burn			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 42 (2.38%)	1 / 43 (2.33%)	
occurrences (all)	1	1	
Congenital, familial and genetic disorders			
polydactyly			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
dizziness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
facial paralysis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
headache			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 42 (9.52%)	1 / 43 (2.33%)	
occurrences (all)	9	2	
migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	2 / 43 (4.65%)	
occurrences (all)	2	2	
paraesthesia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
tension headache			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
tremor			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	2	0	
antiphospholipid syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
lymphadenitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Eye disorders			
conjunctival haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
ocular hyperaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	1 / 43 (2.33%)	
occurrences (all)	1	1	
Gastrointestinal disorders			

abdominal discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
abdominal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
dry mouth			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
dyspepsia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	2	
food poisoning			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
gastritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
nausea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
vomiting			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
ecchymosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
erythema nodosum			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	2	0	
palmar erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
skin lesion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
skin hypopigmentation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
haematuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
costochondritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
fibromyalgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
myalgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	2	0	
joint swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
tenosynovitis stenosans			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
sjogren's syndrome			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
acute sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
bacterial disease carrier			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
bacterial vaginosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[3]	0 / 38 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
bronchitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 42 (7.14%)	0 / 43 (0.00%)	
occurrences (all)	3	0	
covid-19			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 42 (9.52%)	3 / 43 (6.98%)	
occurrences (all)	4	3	
candida infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
cystitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
infected dermal cyst			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)		
occurrences (all)	0	1		
influenza				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 42 (7.14%)	1 / 43 (2.33%)		
occurrences (all)	3	1		
oral herpes				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 42 (7.14%)	0 / 43 (0.00%)		
occurrences (all)	3	0		
nasopharyngitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 42 (4.76%)	1 / 43 (2.33%)		
occurrences (all)	2	1		
mycoplasma infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)		
occurrences (all)	1	0		
otitis media acute				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)		
occurrences (all)	1	0		
pharyngitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)		
occurrences (all)	0	1		
periodontitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)		
occurrences (all)	1	0		
paronychia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)		
occurrences (all)	1	0		

pharyngitis bacterial			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 42 (4.76%)	0 / 43 (0.00%)	
occurrences (all)	2	0	
respiratory tract infection viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
postoperative wound infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
pharyngotonsillitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	2 / 43 (4.65%)	
occurrences (all)	0	2	
sinusitis bacterial			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 42 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[4]	0 / 38 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
vulvovaginitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[5]	1 / 38 (2.63%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
urinary tract infection			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	4 / 42 (9.52%)	6 / 43 (13.95%)	
occurrences (all)	5	6	
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 42 (7.14%)	4 / 43 (9.30%)	
occurrences (all)	3	5	
tooth abscess			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
hyperuricaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 42 (2.38%)	0 / 43 (0.00%)	
occurrences (all)	1	0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

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