



Clinical trial results:

A three-year, open-label extension study of subcutaneous secukinumab to evaluate the long-term efficacy, safety and tolerability in patients with active lupus nephritis

Summary

EudraCT number	2021-005772-19
Trial protocol	ES IT PT SK GR HR
Global end of trial date	23 August 2023

Results information

Result version number	v1 (current)
This version publication date	22 August 2024
First version publication date	22 August 2024

Trial information

Trial identification

Sponsor protocol code	CAIN457Q12301E1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05232864
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.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	23 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 August 2023
Global end of trial reached?	Yes
Global end of trial date	23 August 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of this open-label extension study was to provide treatment with Secukinumab for subjects who completed core study treatment in Study CAIN457Q12301 (NCT04181762), and to obtain further data on long-term efficacy, safety and tolerability of Secukinumab in patients with active lupus nephritis (LN).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 August 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Brazil: 2
Country: Number of subjects enrolled	Colombia: 4
Country: Number of subjects enrolled	Czechia: 2
Country: Number of subjects enrolled	Guatemala: 2
Country: Number of subjects enrolled	Japan: 2
Country: Number of subjects enrolled	Korea, Republic of: 2
Country: Number of subjects enrolled	Philippines: 1
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Slovakia: 1
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	Viet Nam: 7
Worldwide total number of subjects	31
EEA total number of subjects	7

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)	31
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted in 18 centers in 13 countries: Australia (1 site), Brazil (2 sites), Colombia (1 site), Czech Republic (2 sites), Guatemala (2 sites), Japan (2 sites), Korea (1 site), Republic of Philippines (1 site), Portugal (2 sites), Slovakia (Slovak Republic) (1 site), Spain (1 site), Thailand (1 site), Vietnam (1 site)

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Secukinumab 300 mg
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Arm description:

Patients who were on Secukinumab 300 mg in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 281 days)

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	AIN457
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg solution for subcutaneous (s.c.) injection in a 2mL Pre-Filled Syringe (PFS)

Arm title	Placebo to Secukinumab 300 mg
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Arm description:

Patients who were on Placebo in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 310 days)

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	AIN457
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg solution for subcutaneous (s.c.) injection in a 2mL Pre-Filled Syringe (PFS)

Number of subjects in period 1	Secukinumab 300 mg	Placebo to Secukinumab 300 mg
Started	16	15
Completed	0	0
Not completed	16	15
Adverse event, non-fatal	-	1
Study terminated by sponsor	16	14

Baseline characteristics

Reporting groups

Reporting group title	Secukinumab 300 mg
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Reporting group description:

Patients who were on Secukinumab 300 mg in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 281 days)

Reporting group title	Placebo to Secukinumab 300 mg
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Reporting group description:

Patients who were on Placebo in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 310 days)

Reporting group values	Secukinumab 300 mg	Placebo to Secukinumab 300 mg	Total
Number of subjects	16	15	31
Age Categorical Units: Participants			
< 30 years	4	7	11
>= 30 years	12	8	20
Age Continuous Units: Years			
arithmetic mean	35.6	30.6	
standard deviation	± 8.26	± 9.83	-
Sex: Female, Male Units: Participants			
Female	14	14	28
Male	2	1	3
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	6	0	6
Asian	8	8	16
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	2	6	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Secukinumab 300 mg
Reporting group description: Patients who were on Secukinumab 300 mg in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 281 days)	
Reporting group title	Placebo to Secukinumab 300 mg
Reporting group description: Patients who were on Placebo in the Core Study (CAIN457Q12301) and continued treatment with Secukinumab 300 mg every four weeks in the Extension Study until study termination notification (maximum treatment exposure during the extension study: 310 days)	

Primary: Percentage of participants achieving Complete Renal Response (CRR)

End point title	Percentage of participants achieving Complete Renal Response (CRR) ^[1]
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End point description:

Complete Renal Response (CRR) is a composite endpoint defined as:

- Estimated Glomerular Filtration Rate (eGFR) ≥ 60 mL/min/1.73 m² or no less than 85% of core Baseline values and
- 24-hour Urine-to-Protein Creatinine Ratio (UPCR) $= < 0.5$ mg/mg

The glomerular filtration rate was estimated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation based on subject gender, age (years) and serum creatinine (mg/dL). Central laboratory serum creatinine values were used for all renal function data analysis. UPCR was determined by a central laboratory by dividing the protein concentration by the creatinine concentration as measured in the urine collected. UPCR was determined using one of the following two types of urine collection, 24-hour urine collection or first morning void urinary sample, both of which were collected in the subjects' home.

End point type	Primary
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End point timeframe:

Up to 28 weeks: from enrollment in the extension study (Week 104E1) up to Week 132 or Early termination of the Extension Study. Study day is defined with respect to the core study.

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: Only descriptive statistics performed

End point values	Secukinumab 300 mg	Placebo to Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	9		
Units: Participants				
Week 104E1 (n = 9, 9) Responder	4	5		
Week 132 (n = 6, 5) Responder	3	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-treatment adverse events and deaths were reported from first dose of study treatment in the Core Study up to 84 days after last dose of study medication in the Extension Study, assessed up to approximately 3 year.

Adverse event reporting additional description:

Any sign or symptom that occurred during the conduct of the trial and safety follow-up. The Safety Set included all subjects who received at least one dose of study treatment in the extension trial.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Placebo-AIN457 300 mg
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Reporting group description:

Placebo-AIN457 300 mg

Reporting group title	AIN457 300 mg
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Reporting group description:

AIN457 300 mg

Serious adverse events	Placebo-AIN457 300 mg	AIN457 300 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 15 (53.33%)	4 / 16 (25.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Dyspepsia			

subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Lupus nephritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Placebo-AIN457 300 mg	AIN457 300 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)	15 / 16 (93.75%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibrous histiocytoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	2	
Orthostatic hypotension			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Injection site bruising			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Chest discomfort			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Vaccination site pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Peripheral swelling			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Endometriosis			

subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vaginal discharge			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	2	0	
Ovarian cyst			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Menstruation irregular			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hydrometra			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	2 / 15 (13.33%)	2 / 16 (12.50%)	
occurrences (all)	2	2	
Epistaxis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	5	0	
Nasal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)	
occurrences (all)	3	1	
Sneezing			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Upper respiratory tract inflammation			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)	
occurrences (all)	3	1	
Irritability			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Mood swings			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Immunisation reaction			
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)	
occurrences (all)	6	0	
Joint dislocation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Ligament injury			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Limb injury			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Rib fracture subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Vaccination complication subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 2	0 / 16 (0.00%) 0	
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	0 / 16 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	3 / 16 (18.75%) 4	
Cerebral infarction subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Intercostal neuralgia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Memory impairment subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Migraine subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Tension headache subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Tremor subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Dizziness			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	1 / 16 (6.25%) 1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 15 (20.00%)	4 / 16 (25.00%)	
occurrences (all)	3	4	
Iron deficiency anaemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	2	0	
Eye disorders			
Cataract			
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)	
occurrences (all)	2	1	
Dark circles under eyes			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Conjunctivitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Amaurosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Keratitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vision blurred			

subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Visual impairment			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	2	0	
Abdominal discomfort			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Mouth ulceration			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	3	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gingival hypertrophy			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 15 (6.67%)	2 / 16 (12.50%)	
occurrences (all)	1	2	
Gastritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Enteritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	

Diarrhoea			
subjects affected / exposed	4 / 15 (26.67%)	2 / 16 (12.50%)	
occurrences (all)	9	2	
Dental caries			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Aphthous ulcer			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Anal ulcer			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	3 / 16 (18.75%)	
occurrences (all)	0	7	
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Toothache			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
Cholestatic liver injury			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Hepatic steatosis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			

Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	2	
Skin ulcer			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	2 / 15 (13.33%)	2 / 16 (12.50%)	
occurrences (all)	4	2	
Butterfly rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Chloasma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Chronic cutaneous lupus erythematosus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Dermatitis allergic			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Hirsutism			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Nail disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Papule			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Rash erythematous			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Rash pruritic subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Skin lesion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Skin plaque subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Renal and urinary disorders			
Acute kidney injury subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 2	1 / 16 (6.25%) 1	
Lupus nephritis subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 3	0 / 16 (0.00%) 0	
Proteinuria subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 16 (6.25%) 1	
Renal impairment subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Urine abnormality subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Urine odour abnormal subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Musculoskeletal and connective tissue disorders			
Tenosynovitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 16 (0.00%) 0	
Arthralgia			

subjects affected / exposed	3 / 15 (20.00%)	3 / 16 (18.75%)	
occurrences (all)	3	3	
Arthritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal stiffness			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Myositis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Osteochondritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Bacterial vaginosis			
subjects affected / exposed	1 / 15 (6.67%)	2 / 16 (12.50%)	
occurrences (all)	1	2	
Bacteriuria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	

Bronchitis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
COVID-19		
subjects affected / exposed	7 / 15 (46.67%)	5 / 16 (31.25%)
occurrences (all)	7	5
Cystitis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	1	0
Dacryocystitis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Dermatophytosis of nail		
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)
occurrences (all)	1	1
Herpes zoster		
subjects affected / exposed	0 / 15 (0.00%)	5 / 16 (31.25%)
occurrences (all)	0	5
Helicobacter infection		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Gastrointestinal viral infection		
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	1	0
Gastrointestinal infection		
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	1	0
Gastroenteritis		
subjects affected / exposed	2 / 15 (13.33%)	0 / 16 (0.00%)
occurrences (all)	2	0
Fungal foot infection		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Nasopharyngitis		
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)
occurrences (all)	4	2

Onychomycosis		
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	1	0
Oral fungal infection		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Oral herpes		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Otitis media		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Paronychia		
subjects affected / exposed	2 / 15 (13.33%)	1 / 16 (6.25%)
occurrences (all)	2	1
Periodontitis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Pharyngitis		
subjects affected / exposed	3 / 15 (20.00%)	0 / 16 (0.00%)
occurrences (all)	4	0
Pharyngotonsillitis		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Tooth abscess		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1
Upper respiratory tract infection		
subjects affected / exposed	4 / 15 (26.67%)	0 / 16 (0.00%)
occurrences (all)	6	0
Urinary tract infection		
subjects affected / exposed	5 / 15 (33.33%)	4 / 16 (25.00%)
occurrences (all)	7	9
Vaginal infection		
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	1

Varicella			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Viral tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Dyslipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Folate deficiency			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hyperkalaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Hyperlipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hyperuricaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	3 / 15 (20.00%)	1 / 16 (6.25%)	
occurrences (all)	4	1	
Metabolic acidosis			

subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Metabolic syndrome			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Obesity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	

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