



Clinical trial results:

Double-blind, randomised, placebo-controlled, phase II dose-finding study comparing different doses of norucholic acid tablets with placebo in the treatment of primary biliary cholangitis in patients with an inadequate response to ursodeoxycholic acid

Summary

EudraCT number	2021-001431-56
Trial protocol	DE AT FI BE FR NO NL DK
Global end of trial date	12 December 2024

Results information

Result version number	v1 (current)
This version publication date	07 March 2026
First version publication date	07 March 2026

Trial information

Trial identification

Sponsor protocol code	NUT-2/PBC
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dr. Falk Pharma GmbH
Sponsor organisation address	Leinenweberstr. 5, Freiburg, Germany, 79108
Public contact	Dept. of Clinic. Res. & Development, Dr. Falk Pharma GmbH, +49 76115140, zentrale@drfalkpharma.de
Scientific contact	Dept. of Clinic. Res. & Development, Dr. Falk Pharma GmbH, +49 76115140, zentrale@drfalkpharma.de

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	14 January 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 December 2024
Global end of trial reached?	Yes
Global end of trial date	12 December 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of two doses of norucholic acid vs. placebo for the treatment of primary biliary cholangitis (PBC) in patients with an inadequate response to ursodeoxycholic acid (UDCA).

Protection of trial subjects:

Close supervision of subjects by implementing interim visits every 14 days for the first 4 weeks and every 4 weeks up to week 12 and one follow up visit at week 16 to guarantee their safety and wellbeing. Prior to recruitment of patients, all relevant documents of the clinical study were submitted and approved by the Independent Ethics Committees (IECs) responsible for the participating investigators. Written consent documents embodied the elements of informed consent as described in the Declaration of Helsinki, the ICH Guidelines for Good Clinical Practice (GCP) and were in accordance with all applicable laws and regulations. The informed consent form and patient information sheet described the planned and permitted uses, transfers and disclosures of the patient's personal data and personal health information for purposes of conducting the study. The informed consent form and the patient information sheet further explained the nature of the study, its objectives and potential risks and benefits as well as the date informed consent was given. Before being enrolled in the clinical trial, every patient was informed that participation in this trial was voluntary and that he/she could withdraw from the study at any time without giving a reason and without having to fear any loss in his/her medical care. The patient's consent was obtained in writing before the start of the study. By signing the informed consent, the patient declared that he/she was participating voluntarily and intended to follow the study protocol instructions and the instructions of the investigator and to answer the questions asked during the course of the trial. Additionally, an IDMC was implemented to evaluate the safety data of the clinical study.

Background therapy:

All patients were to continue their pre-trial dose of UDCA throughout trial participation without changing the dosing regimen.

Evidence for comparator:

As all patients will continue standard care treatment with UDCA, a placebo arm will be included as control due to regulatory recommendations to evaluate dose-related benefits and adverse effects in randomised, double-blind, placebo controlled studies.

Actual start date of recruitment	03 January 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	Netherlands: 4
Country: Number of subjects enrolled	Norway: 1
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 2

Country: Number of subjects enrolled	Denmark: 8
Country: Number of subjects enrolled	Finland: 4
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Switzerland: 10
Country: Number of subjects enrolled	United Kingdom: 11
Worldwide total number of subjects	77
EEA total number of subjects	56

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)	63
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In total 77 patients were included in Austria, Belgium, Switzerland, Germany, Denmark, Finland, France, United Kingdom, the Netherlands, Norway and Poland from September 2022 to July 2024.

Pre-assignment

Screening details:

A total of 99 patients were screened for the trial, 20 of whom were screening failures. A total of 79 patients were randomized. 77 were treated and included in the full analysis set.

Period 1

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

Blinding implementation details:

Blinding was achieved by the application of the same number of tablets (verum and/or placebo) to each participant, i.e., each participant received a total of 3 tablets per day. Placebo tablets corresponded to verum tablets in size, taste and appearance.

Arms

Are arms mutually exclusive?	Yes
Arm title	NCA high

Arm description:

NCA 1500 mg once daily, 3 NCA tablets of 500 mg

Arm type	Experimental
Investigational medicinal product name	NCA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

NCA 1500 mg once daily

3 tablets à 500 mg NCA to be taken orally once daily

Arm title	NCA low
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Arm description:

NCA 1000 mg once daily, 2 NCA tablets of 500 mg and 1 Placebo tablet

Arm type	Experimental
Investigational medicinal product name	NCA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000 mg NCA once daily

2 tablets à 500 mg NCA + 1 tablet Placebo to be taken orally once daily

Arm title	Placebo
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Arm description:

Placebo

Arm type	Placebo
Investigational medicinal product name	Placebo for NCA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo for NCA once daily

3 tablets of Placebo to be taken orally once daily

Number of subjects in period 1	NCA high	NCA low	Placebo
Started	26	26	25
Completed	25	24	23
Not completed	1	2	2
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	2	-
Lack of compliance	1	-	1

Baseline characteristics

Reporting groups

Reporting group title	Treatment Phase (overall trial/period)
Reporting group description:	
79 patients were randomized. 2 patients have been randomized but not treated. Baseline characteristics are only reported for the 77 patients having received treatment.	

Reporting group values	Treatment Phase (overall trial/period)	Total	
Number of subjects	77	77	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	63	63	
From 65-84 years	14	14	
85 years and over	0	0	
Age continuous			
Units: years			
median	55		
full range (min-max)	21 to 74	-	
Gender categorical			
Units: Subjects			
Female	71	71	
Male	6	6	

End points

End points reporting groups

Reporting group title	NCA high
Reporting group description: NCA 1500 mg once daily, 3 NCA tablets of 500 mg	
Reporting group title	NCA low
Reporting group description: NCA 1000 mg once daily, 2 NCA tablets of 500 mg and 1 Placebo tablet	
Reporting group title	Placebo
Reporting group description: Placebo	

Primary: Mean relative change (%) in ALP between the baseline visit and the EOT visit

End point title	Mean relative change (%) in ALP between the baseline visit and the EOT visit
End point description:	
End point type	Primary
End point timeframe: 12 weeks treatment: from Baseline to end of treatment, LOCF (last observation carried forward)	

End point values	NCA high	NCA low	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	26	26	25	
Units: %				
arithmetic mean (confidence interval 95%)	-4.998 (-16.3653 to 6.3699)	1.548 (-7.9182 to 11.0135)	-6.652 (-13.5321 to 0.2273)	

Statistical analyses

Statistical analysis title	NCA high vs. Placebo
Comparison groups	NCA high v Placebo
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Median difference (final values)
Point estimate	-1.91

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-11.11
upper limit	7.28

Statistical analysis title	NCA low vs. Placebo
Comparison groups	NCA low v Placebo
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Median difference (final values)
Point estimate	8.62
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-2.26
upper limit	19.49

Secondary: Mean relative change (%) in ALP between the baseline visit and the EOT visit

End point title	Mean relative change (%) in ALP between the baseline visit and the EOT visit ^[1]
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End point description:

End point type	Secondary
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End point timeframe:

12 week treatment: from Baseline to end of treatment, LOCF (last observation carried forward)

Notes:

[1] - 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: The comparison of the other arms are reported in the primary endpoint. In this secondary endpoint the additional comparison between NCA high and NCA low is analyzed and reported.

End point values	NCA high	NCA low		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	26		
Units: %				
arithmetic mean (confidence interval 95%)	-4.998 (-16.3653 to 6.3699)	1.548 (-7.9182 to 11.0135)		

Statistical analyses

Statistical analysis title	NCA high vs. NCA low
Comparison groups	NCA high v NCA low
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Median difference (final values)
Point estimate	-11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.93
upper limit	-2.27

Secondary: Partial normalization of serum alkaline phosphatase (ALP)

End point title	Partial normalization of serum alkaline phosphatase (ALP)
End point description:	Partial normalization of ALP [U/L] (<1.5x ULN) at any Visit during the treatment phase
End point type	Secondary
End point timeframe:	12 weeks treatment: from Baseline to end of treatment, LOCF (last observation carried forward)

End point values	NCA high	NCA low	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	26	26	25	
Units: Patients	6	2	3	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were assessed at V1 (Baseline visit), V2, V3, V4, V5 (End of Treatment visit) and V6 (Follow-Up Visit).

Adverse event reporting additional description:

Treatment emergent adverse events

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	NCA high
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Reporting group description: -

Reporting group title	NCA low
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	NCA high	NCA low	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	1 / 25 (4.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Surgical and medical procedures			
Gastrectomy			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (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
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haemorrhage			

subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental disorder			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	NCA high	NCA low	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 26 (88.46%)	21 / 26 (80.77%)	19 / 25 (76.00%)
Vascular disorders			
Aortic arteriosclerosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Salpingectomy			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin lesion removal			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	2
Fatigue			

subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	2 / 26 (7.69%) 2	3 / 25 (12.00%) 4
Influenza like illness subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Immune system disorders Contrast media reaction subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 2	0 / 25 (0.00%) 0
Psychiatric disorders Agitation subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Emotional disorder subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Insomnia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	2 / 26 (7.69%) 2	0 / 25 (0.00%) 0
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0

Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Blood folate decreased subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Coagulation test abnormal subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Electrocardiogram abnormal subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Injury, poisoning and procedural complications Alcohol poisoning subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Ankle fracture subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Post procedural haematoma subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Skin wound subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Cardiac disorders Mitral valve incompetence subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Head discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	3 / 25 (12.00%)
occurrences (all)	1	3	3
Migraine			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Nerve compression			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Vertigo			

subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Eye swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Retinal detachment			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Abdominal distension			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Abdominal pain lower			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Abdominal tenderness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Breath odour			

subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Change of bowel habit			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 26 (0.00%)	2 / 26 (7.69%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	6 / 25 (24.00%)
occurrences (all)	1	3	7
Dry mouth			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	2 / 26 (7.69%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Dysphagia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Faeces discoloured			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 26 (0.00%)	2 / 26 (7.69%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Haemorrhoids			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Nausea			

subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 3	3 / 26 (11.54%) 3	1 / 25 (4.00%) 1
Tooth impacted subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	1 / 25 (4.00%) 1
Hepatobiliary disorders			
Cholelithiasis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	1 / 25 (4.00%) 1
Hepatic cirrhosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	2 / 25 (8.00%) 2
Hepatic fibrosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Hepatitis cholestatic subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Liver disorder subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Ocular icterus subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	0 / 25 (0.00%) 0
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Alopecia			

subjects affected / exposed	2 / 26 (7.69%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Dry skin			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Erythema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	3 / 26 (11.54%)	9 / 26 (34.62%)	2 / 25 (8.00%)
occurrences (all)	6	9	2
Psoriasis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Purpura			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	3 / 26 (11.54%)	2 / 26 (7.69%)	2 / 25 (8.00%)
occurrences (all)	3	2	2
Rash maculo-papular			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Skin burning sensation			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin discolouration			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Telangiectasia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	3 / 26 (11.54%)	2 / 26 (7.69%)	2 / 25 (8.00%)
occurrences (all)	3	2	2
Arthritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Scoliosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	2 / 26 (7.69%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Coronavirus infection			

subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 26 (3.85%)	4 / 26 (15.38%)	0 / 25 (0.00%)
occurrences (all)	1	5	0
Erysipelas			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Genital infection fungal			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	5 / 26 (19.23%)	5 / 26 (19.23%)	3 / 25 (12.00%)
occurrences (all)	5	5	3
Sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	3
Viral upper respiratory tract infection			

subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Increased appetite			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0

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