



## Clinical trial results:

### A Phase 2a, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-67484703 in Participants with Atopic Dermatitis Summary

EudraCT number	2022-001528-14
Trial protocol	PL DE
Global end of trial date	14 May 2024

#### Results information

Result version number	v1 (current)
This version publication date	19 June 2025
First version publication date	19 June 2025

#### Trial information

##### Trial identification

Sponsor protocol code	67484703ADM2001
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	14 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 May 2024
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the efficacy of JNJ-67484703 in subjects with moderate to severe atopic dermatitis (AD).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 February 2023
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	Germany: 25
Country: Number of subjects enrolled	Poland: 16
Country: Number of subjects enrolled	Canada: 10
Worldwide total number of subjects	51
EEA total number of subjects	41

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)	50
From 65 to 84 years	1

85 years and over	0
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## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 51 subjects were enrolled, randomised (2:1 ratio) and treated either with JNJ-67484703 or placebo. Out of 51 subjects, 30 subjects completed the study.

### 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
<b>Arm title</b>	Arm A: Placebo

Arm description:

Subjects received a single dose of placebo subcutaneous (SC) injection at Week 0 (Day 1), a loading dose at Week 1, followed by once every 2 weeks (Q2W) from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10.

<b>Arm title</b>	Arm B: JNJ-67484703
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Arm description:

Subjects received a single dose of JNJ-67484703 3 milligrams per kilogram (mg/kg) SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Arm type	Experimental
Investigational medicinal product name	JNJ-67484703
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received JNJ-67484703 3 mg/kg SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10.

<b>Number of subjects in period 1</b>	Arm A: Placebo	Arm B: JNJ-67484703
Started	17	34
Completed	9	21
Not completed	8	13
Consent withdrawn by subject	8	10
COVID-19 related	-	3

## Baseline characteristics

### Reporting groups

Reporting group title	Arm A: Placebo
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Reporting group description:

Subjects received a single dose of placebo subcutaneous (SC) injection at Week 0 (Day 1), a loading dose at Week 1, followed by once every 2 weeks (Q2W) from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Reporting group title	Arm B: JNJ-67484703
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Reporting group description:

Subjects received a single dose of JNJ-67484703 3 milligrams per kilogram (mg/kg) SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Reporting group values	Arm A: Placebo	Arm B: JNJ-67484703	Total
Number of subjects	17	34	51
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	35.5 ± 12.78	35.2 ± 11.65	-
Gender categorical Units: Subjects			
Male	9	15	24
Female	8	19	27
Race Units: Subjects			
Asian	1	7	8
White	15	27	42
Multiple	1	0	1
Ethnicity Units: Subjects			
Not Hispanic or Latino	17	34	51

## End points

### End points reporting groups

Reporting group title	Arm A: Placebo
Reporting group description: Subjects received a single dose of placebo subcutaneous (SC) injection at Week 0 (Day 1), a loading dose at Week 1, followed by once every 2 weeks (Q2W) from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.	
Reporting group title	Arm B: JNJ-67484703
Reporting group description: Subjects received a single dose of JNJ-67484703 3 milligrams per kilogram (mg/kg) SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.	

### Primary: Percentage of Subjects Who Achieved Eczema Area and Severity Index (EASI)-75 at Week 12

End point title	Percentage of Subjects Who Achieved Eczema Area and Severity Index (EASI)-75 at Week 12
End point description: Percentage of subjects who achieved EASI-75 at Week 12 were reported. EASI-75 response was defined as at least 75 percent (%) improvement from baseline in EASI total score. The EASI score was used to measure the severity and extent of atopic dermatitis (AD) and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head or neck, trunk, upper and lower limbs. The total EASI score ranged from 0 (minimum) to 72 (maximum) points, with the higher scores indicated the worse severity of AD. Full analysis set (FAS) included all randomised subjects who had received at least 1 dose of study intervention and provided both baseline and at least 1 postbaseline data.	
End point type	Primary
End point timeframe: Week 12	

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	32		
Units: Percentage of subjects				
number (not applicable)	11.8	25.0		

### Statistical analyses

Statistical analysis title	Statistical Analysis-1
Comparison groups	Arm B: JNJ-67484703 v Arm A: Placebo

Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.459
Method	Fisher exact
Parameter estimate	Treatment difference
Point estimate	13.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.8
upper limit	31.2

### Secondary: Percentage of Subjects With Improvement (Reduction From Baseline) in Eczema Related Itch Numeric Rating Scale (NRS) Score of $\geq 4$ at Week 12 Among Subjects With a Baseline Itch Value $\geq 4$

End point title	Percentage of Subjects With Improvement (Reduction From Baseline) in Eczema Related Itch Numeric Rating Scale (NRS) Score of $\geq 4$ at Week 12 Among Subjects With a Baseline Itch Value $\geq 4$
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#### End point description:

Percentage of subjects with improvement (reduction from baseline) in eczema-related itch NRS score of  $\geq 4$  at Week 12 among subjects with a baseline itch value  $\geq 4$  was reported. The eczema skin pain and Itch NRS is a 3-item patient-reported outcome that subjects used to rate the severity of their eczema-related skin pain and eczema related itch daily. Subjects were asked the following questions: please rate the severity of eczema-related itch at its worst in the past 24 hours. Each item was on a 0 to 10 NRS ranging from 0 "none" to 10 "worst possible". Higher score indicated more severity. FAS included all randomised subjects who had received at least 1 dose of study intervention and provided both baseline and at least 1 postbaseline data.

End point type	Secondary
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#### End point timeframe:

Week 12

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	26		
Units: Percentage of subjects				
number (not applicable)	13.3	11.5		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Achieved Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) of 0 or 1 and a Reduction From Baseline of $\geq 2$ Points at Week 12

End point title	Percentage of Subjects Who Achieved Validated Investigator
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## End point description:

Percentage of subjects who achieved vIGA-AD of 0 or 1 and a reduction from baseline of  $\geq 2$  points at Week 12 were reported. It was an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranged from 0 to 4, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification. No oozing or crusting; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/ papulation and/or lichenification, oozing or crusting may present, 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher score indicated more severity of AD. FAS included all randomised subjects who had received at least 1 dose of study intervention and provide both baseline and at least 1 postbaseline data.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	32		
Units: Percentage of subjects				
number (not applicable)	5.9	6.3		

## Statistical analyses

No statistical analyses for this end point

**Secondary: Percentage of Subjects Who Achieved Eczema Area and Severity Index (EASI)-90 at Week 12**

End point title	Percentage of Subjects Who Achieved Eczema Area and Severity Index (EASI)-90 at Week 12
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## End point description:

Percentage of subjects who achieved EASI-90 at Week 12 were reported. EASI-90 response was defined as at least 90% improvement from baseline in EASI total score. The EASI score was used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head/neck, trunk, upper and lower limbs. The total EASI score ranged from 0 (minimum) to 72 (maximum) points, with the higher scores indicated the worse severity of AD. FAS included all randomised subjects who had received at least 1 dose of study intervention and provided both baseline and at least 1 postbaseline data.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	32		
Units: Percentage of subjects				
number (not applicable)	5.9	9.4		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percent Change from Baseline in Eczema Related Itch Score (item 2 on Eczema Skin Pain and Itch Numeric Rating Scale [ESPI NRS]) at Weeks 1, 4, and 6

End point title	Percent Change from Baseline in Eczema Related Itch Score (item 2 on Eczema Skin Pain and Itch Numeric Rating Scale [ESPI NRS]) at Weeks 1, 4, and 6
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End point description:

The eczema skin pain and Itch NRS is a 3-item patient-reported outcome that subjects used to rate the severity of their eczema-related skin pain and eczema related itch daily. Subjects were asked the following questions: please rate the severity of eczema-related itch at its worst in the past 24 hours. Each item was on a 0 to 10 NRS ranging from 0 "none" to 10 "worst possible". Higher score indicated more severity. FAS included all randomised subjects who had received at least 1 dose of study intervention and provided both baseline and at least 1 postbaseline data. Here, 'N' (number of subjects analysed) signifies subjects who were evaluable for this endpoint and 'n': number of subjects evaluable at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 1, 4, and 6

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	27		
Units: Percent change				
arithmetic mean (standard deviation)				
Week 1 (n=13, 27)	-4.21 (± 18.668)	3.84 (± 40.641)		
Week 4 (n=14, 27)	-4.84 (± 13.706)	-6.86 (± 49.608)		
Week 6 (n=14, 27)	-13.36 (± 28.879)	-11.43 (± 46.763)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percent Change from Baseline in Eczema Area and Severity Index (EASI) Score at Week 12

End point title	Percent Change from Baseline in Eczema Area and Severity Index (EASI) Score at Week 12
End point description:	
Percent change from baseline in EASI scores in Week 12 were reported. The EASI evaluation was performed by the Principal Investigator. The EASI score was used to measure the severity and extent of atopic dermatitis (AD) and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head or neck, trunk, upper and lower limbs. The total EASI score ranged from 0 (minimum) to 72 (maximum) points, with the higher scores indicated the worse severity of AD. FAS included all randomised subjects who had received at least 1 dose of study intervention and provided both baseline and at least 1 postbaseline data. Here, 'N' (number of subjects analysed) signifies subjects who were evaluable for this endpoint.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

<b>End point values</b>	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	30		
Units: Percent change				
arithmetic mean (standard deviation)	-21.66 (± 42.777)	-42.31 (± 39.273)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Percentage of Subjects With Treatment-emergent Adverse Events (TEAEs)
End point description:	
An adverse event (AE) was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal (investigational or non-investigational) product. TEAE were AEs with onset after or on the date of the first dose of the study intervention or that were a consequence of a pre-existing condition that had worsened since baseline. The safety analysis set included all randomised subjects who had received at least 1 dose of study intervention.	
End point type	Secondary
End point timeframe:	
From Day 1 up to Week 36	

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	34		
Units: Percentage of subjects				
number (not applicable)	82.4	88.2		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With Treatment-emergent Serious Adverse Events (TESAEs)

End point title	Percentage of Subjects With Treatment-emergent Serious Adverse Events (TESAEs)
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End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. Serious adverse events (SAE) is any AE that results in: death, persistent or significant disability/incapacity, requires inpatient hospitalisation or prolongation of existing hospitalisation, is life-threatening experience, is a congenital anomaly/birth defect and may jeopardize subject and/or may require medical or surgical intervention to prevent one of the outcomes listed above. TESAE were SAEs with onset after or on the date of the first dose of the study intervention or that were a consequence of a pre-existing condition that had worsened since baseline. The safety analysis set included all randomised subjects who had received at least 1 dose of study intervention.

End point type	Secondary
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End point timeframe:

From Day 1 up to Week 36

End point values	Arm A: Placebo	Arm B: JNJ-67484703		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	34		
Units: Percentage of subjects				
number (not applicable)	0	2.9		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Death: From screening (Week-5) to Week 36 (26 weeks after last dose at Week 10); SAE and Non-serious AEs: From Day 1 up to Week 36 (26 weeks after last dose at Week 10)

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who had received at least 1 dose of study intervention.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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### Reporting groups

Reporting group title	Arm B: JNJ-67484703
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Reporting group description:

Subjects received a single dose of JNJ-67484703 3 milligrams per kilogram (mg/kg) SC injection at Week 0 (Day 1), a loading dose at Week 1, followed by once Q2W from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Reporting group title	Arm A: Placebo
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Reporting group description:

Subjects received a single dose of placebo subcutaneous (SC) injection at Week 0 (Day 1), a loading dose at Week 1, followed by once every 2 weeks (Q2W) from Week 2 until Week 10. Subjects were then follow-up for safety up to 26 weeks after the administration of the last dose of study drug at Week 10.

Serious adverse events	Arm B: JNJ-67484703	Arm A: Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 34 (2.94%)	0 / 17 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 34 (2.94%)	0 / 17 (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: 5 %

Non-serious adverse events	Arm B: JNJ-67484703	Arm A: Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 34 (73.53%)	14 / 17 (82.35%)	

Investigations			
Vitamin B12 Decreased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
C-Reactive Protein Increased			
subjects affected / exposed	2 / 34 (5.88%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Blood Triglycerides Increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	2 / 34 (5.88%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Blood Iron Decreased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Blood Glucose Increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 34 (23.53%)	1 / 17 (5.88%)	
occurrences (all)	8	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Microcytic Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Swelling Face			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Gastrointestinal disorders			

Aphthous Ulcer subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	
Dyspepsia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	
Toothache subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 17 (5.88%) 1	
Diarrhoea subjects affected / exposed occurrences (all)	3 / 34 (8.82%) 3	0 / 17 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)  Dermatitis Atopic subjects affected / exposed occurrences (all)  Urticaria subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0  8 / 34 (23.53%) 9  0 / 34 (0.00%) 0	1 / 17 (5.88%) 1  3 / 17 (17.65%) 4  1 / 17 (5.88%) 1	
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	
Musculoskeletal and connective tissue disorders Muscle Tightness subjects affected / exposed occurrences (all)  Arthralgia	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 17 (5.88%) 1	
Infections and infestations			
Oral Herpes			
subjects affected / exposed	4 / 34 (11.76%)	0 / 17 (0.00%)	
occurrences (all)	4	0	
Nasopharyngitis			
subjects affected / exposed	7 / 34 (20.59%)	5 / 17 (29.41%)	
occurrences (all)	8	8	
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Furuncle			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Covid-19			
subjects affected / exposed	2 / 34 (5.88%)	2 / 17 (11.76%)	
occurrences (all)	2	2	
Gastrointestinal Infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 34 (8.82%)	0 / 17 (0.00%)	
occurrences (all)	4	0	
Staphylococcal Skin Infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Urinary Tract Infection			
subjects affected / exposed	1 / 34 (2.94%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported