Clinical trial results:
An Open-label, Multi-center Extension Study to Evaluate the Long-term Safety and Efficacy of Deucravacitinib in Participants with Moderate to Severe Crohn's Disease or Moderate to Severe Ulcerative Colitis

Summary

EudraCT number	2020-004461-40
Trial protocol	DE IT ES PT NL
Global end of trial date	29 August 2023

Results information

Result version number	v1 (current)
This version publication date	13 September 2024
First version publication date	13 September 2024

Trial information

Trial identification

Sponsor protocol code	IM011-077

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	01 November 2023
Is this the analysis of the primary completion data?	No

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

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of long-term use of deucravacitinib in participants with moderate to severe CD

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 May 2021
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	Canada: 1
Country: Number of subjects enrolled	China: 2
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Japan: 4
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	67
EEA total number of subjects	42

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)	59
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
67 subjects randomized

Period 1

Period 1 title	Pre-treatment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Crohn’s Disease

Arm description:
Deucravacitinib (BMS-986165) 6 mg twice daily (BID)

Arm type	Experimental
Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	BMS-986165
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
6 mg twice daily (BID)

Arm title	Ulcerative Colitis

Arm description:
Deucravacitinib (BMS-986165) 6 mg twice daily (BID)

Arm type	Experimental
Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	BMS-986165
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
6 mg twice daily (BID)

Number of subjects in period 1	Crohn’s Disease	Ulcerative Colitis
Started	26	41
Completed	24	41
Not completed	2	0
Other reasons	2	-

Period 2	
Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Crohn’s Disease

Arm description:

Deucravacitinib (BMS-986165) 6 mg twice daily (BID)

Arm type	Experimental
Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	BMS-986165
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6 mg twice daily (BID)

Arm title	Ulcerative Colitis

Arm description:

Deucravacitinib (BMS-986165) 6 mg twice daily (BID)

Arm type	Experimental
Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	BMS-986165
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6 mg twice daily (BID)

Number of subjects in period 2	Crohn’s Disease	Ulcerative Colitis
Started	24	41
Completed	0	0
Not completed	24	41
Consent withdrawn by subject	2	6
Adverse Event	2	1
Other reasons	3	1
Administrative reasons by sponsor	17	33

Baseline characteristics

Reporting groups	
Reporting group title	Crohn’s Disease
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	
Reporting group title	Ulcerative Colitis
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	

Reporting group values	Crohn’s Disease	Ulcerative Colitis	Total
Number of subjects	26	41	67
Age categorical Units:			
Age Continuous Units: years			
arithmetic mean	38.7	44.3	
standard deviation	± 14.08	± 15.70	-
Sex: Female, Male Units: Participants			
Female	10	19	29
Male	16	22	38
Race/Ethnicity, Customized Units: Subjects			
White	21	38	59
Black or African American	1	0	1
Asian	2	0	2
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Asian Indian	0	0	0
Chinese	2	0	2
Japanese	0	3	3
Asian Other	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	21	35	56
Unknown or Not Reported	5	5	10

End points

End points reporting groups

Reporting group title	Crohn’s Disease
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	
Reporting group title	Ulcerative Colitis
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	
Reporting group title	Crohn’s Disease
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	
Reporting group title	Ulcerative Colitis
Reporting group description: Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	

Primary: Number of Participants with Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs)

End point title	Number of Participants with Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs)[1]

End point description:

Number of participants experiencing AEs, SAEs, AEs leading to study discontinuation, and AEs of interest (AEIs). An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. SAEs is any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires inpatient hospitalization; results significant disability; or is a congenital anomaly/birth defect. TEAEs are defined as AEs with an onset date on or after the first dose of study treatment up to 30 days after the last dose of study treatment in the study, or if a pre-existing condition worsens in severity or becomes serious after receiving the first dose of study treatment

End point type	Primary

End point timeframe:

From first dose to 30 days post last dose (Up to 110 weeks)

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 summary statistics planned for this endpoint

End point values	Crohn’s Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	41		
Units: Participants				
TEAEs	18	19		
TESAEs	2	2		
TEAEs leading to study discontinuation	1	1		
AEs of Interest - Skin-related events	0	2		
AEs of Interest - Creatine Kinase events	2	3		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Laboratory Abnormalities

End point title	Number of Participants with Laboratory Abnormalities[2]

End point description:

Number of participants experiencing abnormalities in laboratory testing including chemistry, hematology, and renal.

End point type	Primary

End point timeframe:

From first dose to 30 days post last dose (Up to 110 weeks)

Notes:

[2] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	41		
Units: Participants				
Sodium < 130 or > 150 MEQ/L (MMOL/L)	0	0		
Potassium < 3 or > 5.5 MEQ/L (MMOL/L)	0	1		
Calcium > 12.5 MG/DL	0	0		
Fasting Serum Glucose < 50 MG/DL or > 250 MG/DL	0	0		
Albumin < 2.0 G/DL	0	0		
Creatine Kinase > 10xupper limit of normal	0	0		
Hemoglobin < 7.0 G/DL or > 30% reduction	0	0		
Hematocrit < 20% or 30% reduction	0	0		
White Blood Cell < 1.5 x 10^9/L or > 35 x 10^9/L	0	0		
Lymphocyte Count < 0.5 x 10^9/L	0	0		
Neutrophil Count < 0.75 x 10^9/L	0	0		
Platelet Count < 75 x 10^9/L or > 999 x 10^9/L	0	0		
Serum Creatinine Increase > 50% and > 44.2 UMOL/L	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Electrocardiogram (ECG) Abnormalities

End point title	Number of Participants with Electrocardiogram (ECG) Abnormalities[3]

End point description:

End point type	Primary

End point timeframe:

From first dose to 30 days post last dose (Up to 110 weeks)

Notes:

[3] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	41		
Units: Participants				
QTCF (MSEC) 450 - < 480	1	0		
QTCF (MSEC) 480 - < 500	0	1		
QTCF (MSEC) >= 500	0	0		
30 < CHANGE FROM IM011077 BASELINE <= 60 MSEC	3	0		
CHANGE FROM IM011077 BASELINE > 60 MSEC	3	5		
PRAG P WAVE AND R WAVE (PR) INTERVAL >= 240 MSEC	0	0		
QRSAG QRS INTERVAL >= 200 MSEC	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Vital Signs Abnormalities

End point title	Number of Participants with Vital Signs Abnormalities[4]

End point description:

End point type	Primary

End point timeframe:

From first dose to 30 days post last dose (Up to 110 weeks)

Notes:

[4] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	41		
Units: Participants				
HR: VALUE > 100 AND CHANGE FROM BASELINE > 30	1	1		
HR: VALUE < 55 AND CHANGE FROM BASELINE < -15	1	0		
SYSTOLIC BP: > 140 AND CHANGE FROM BASELINE > 20	3	5		
SYSTOLIC BP: < 90 AND CHANGE FROM BASELINE < -20	0	0		
DIASTOLIC BP: > 90 AND CHANGE FROM BASELINE > 10	3	5		
DIASTOLIC BP: < 55 AND CHANGE FROM BASELINE < -10	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Laboratory Parameters

End point title	Change from Baseline in Laboratory Parameters[5]

End point description:

Change from baseline in laboratory parameters including lipid profile, chemistry liver function, chemistry (other), and chemistry renal function.
99999=NA
00000= 0 subjects analyzed

End point type	Primary

End point timeframe:

Baseline, Week 12, Week 108

Notes:

[5] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	38		
Units: mg/dL				
arithmetic mean (standard error)				
Cholesterol, Fasting Week 12	10.20 (± 7.207)	-9.17 (± 4.629)		
Cholesterol, Fasting Week 108	-12.00 (± 99999)	00000 (± 00000)		
HDL Cholesterol, Fasting Week 12	-0.75 (± 3.400)	-0.83 (± 2.626)		
HDL Cholesterol, Fasting Week 108	0.00 (± 99999)	00000 (± 00000)		
LDL Cholesterol, Fasting Week 12	4.75 (± 4.270)	-6.50 (± 4.689)		
LDL Cholesterol, Fasting Week 108	1.00 (± 99999)	00000 (± 00000)		

Triglycerides, Fasting Week 12	2.3 (± 11.31)	3.2 (± 4.78)		
Triglycerides, Fasting Week 108	-62.0 (± 99999)	00000 (± 00000)		
Bilirubin, Week 12	0.0650 (± 0.05028)	0.0043 (± 0.03566)		
Bilirubin, Week 108	-0.1000 (± 0.00000)	00000 (± 00000)		
Glucose, Fasting Serum Week 12	1.75 (± 0.946)	0.80 (± 1.114)		
Glucose, Fasting Serum Week 108	29.00 (± 99999)	00000 (± 00000)		
Calcium, Week 12	0.152 (± 0.0915)	0.041 (± 0.0612)		
Calcium, Week 108	0.350 (± 0.1500)	00000 (± 00000)		
Creatinine, Week 12	-0.008 (± 0.0182)	0.004 (± 0.0153)		
Creatinine, Week 108	0.080 (± 0.0100)	00000 (± 00000)		
Phosphate, Week 12	0.153 (± 0.0893)	0.019 (± 0.1198)		
Phosphate, Week 108	-0.150 (± 0.1500)	00000 (± 00000)		
Urea Nitrogen, Week 12	-0.269 (± 1.0631)	0.511 (± 0.5902)		
Urea Nitrogen, Week 108	5.500 (± 0.5000)	00000 (± 00000)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Electrocardiogram (ECG) Parameters - ECG Mean Heart Rate

End point title	Change from Baseline in Electrocardiogram (ECG) Parameters - ECG Mean Heart Rate[6]

End point description:

Changes from IM011077 study baseline in electrocardiogram (ECG) parameters - ECG mean heart rate. 99999=NA

End point type	Primary

End point timeframe:

Baseline, Week 48, Week 96

Notes:

[6] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	17		
Units: beats/min				
arithmetic mean (standard deviation)				
ECG Mean Heart Rate, Week 48	-1.4 (± 9.21)	2.6 (± 12.76)		
ECG Mean Heart Rate, Week 96	-1.0 (± 11.27)	-1.0 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Electrocardiogram (ECG) Parameters

End point title	Change from Baseline in Electrocardiogram (ECG) Parameters[7]

End point description:

Changes from IM011077 study baseline in electrocardiogram (ECG) parameters.
99999=NA
00000= 0 subjects analyzed

End point type	Primary

End point timeframe:

Baseline, Week 48, Week 96

Notes:

[7] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	16		
Units: msec				
arithmetic mean (standard deviation)				
PR Interval, Aggregate, Week 48	9.1 (± 20.62)	-2.4 (± 22.65)		
PR Interval, Aggregate, Week 96	14.7 (± 16.56)	-22.0 (± 99999)		
QRS Duration, Aggregate, Week 48	-1.2 (± 8.47)	-0.9 (± 8.53)		
QRS Duration, Aggregate, Week 96	-9.3 (± 2.89)	0.0 (± 99999)		
QT Interval, Aggregate, Week 48	18.6 (± 30.33)	7.6 (± 40.35)		
QT Interval, Aggregate, Week 96	27.0 (± 62.55)	96.0 (± 99999)		
QTcB Interval, Aggregate, Week 48	-2.3 (± 21.78)	7.7 (± 19.41)		
QTcB Interval, Aggregate, Week 96	00000 (± 00000)	00000 (± 00000)		
QTcF Interval, Aggregate, Week 48	-20.6388 (± 197.49472)	31.1621 (± 141.14597)		
QTcF Interval, Aggregate, Week 96	-86.9797 (± 198.61888)	101.0000 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Vital Signs Parameters - Heart Rate

End point title	Change from Baseline in Vital Signs Parameters - Heart Rate[8]

End point description:

Changes from IM011077 study baseline in vital signs parameters - heart rate.
99999=NA
00000= 0 subjects analyzed

End point type	Primary

End point timeframe:

Baseline, Week 12, Week 108

Notes:

[8] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	41		
Units: beats/min				
arithmetic mean (standard deviation)				
Heart Rate Week 12	3.6 (± 11.89)	0.9 (± 10.71)		
Heart Rate Week 108	1.0 (± 99999)	00000 (± 00000)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Vital Signs Parameters

End point title	Change from Baseline in Vital Signs Parameters[9]

End point description:

Changes from IM011077 study baseline in vital signs parameters.
99999=NA
00000= 0 subjects analyzed

End point type	Primary

End point timeframe:

Baseline, Week 12, Week 108

Notes:

[9] - 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 summary statistics planned for this endpoint

End point values	Crohn's Disease	Ulcerative Colitis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	41		
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure Week 12	3.8 (± 11.56)	3.8 (± 13.62)		
Systolic Blood Pressure Week 108	4.0 (± 99999)	00000 (± 00000)		
Diastolic Blood Pressure Week 12	0.3 (± 7.82)	-1.3 (± 7.38)		
Diastolic Blood Pressure Week 108	9.0 (± 99999)	00000 (± 00000)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs are assessed from first dose to 30 days post last dose (Up to 110 weeks). Participants were assessed for deaths (all-causes) from their first dose to study completion (Up to 120 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Crohn’s Disease
Reporting group description:	
Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	
Reporting group title	Ulcerative Colitis
Reporting group description:	
Deucravacitinib (BMS-986165) 6 mg twice daily (BID)	

Serious adverse events	Crohn’s Disease	Ulcerative Colitis	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)	2 / 41 (4.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Procedural pneumothorax			
subjects affected / exposed	0 / 24 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 24 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 24 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 24 (4.17%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 41 (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	Crohn’s Disease	Ulcerative Colitis	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 24 (50.00%)	13 / 41 (31.71%)	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 24 (8.33%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
Gastrointestinal disorders			
Colitis ulcerative			

subjects affected / exposed	0 / 24 (0.00%)	3 / 41 (7.32%)	
occurrences (all)	0	3	
Mouth ulceration			
subjects affected / exposed	2 / 24 (8.33%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 24 (8.33%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 24 (0.00%)	3 / 41 (7.32%)	
occurrences (all)	0	3	
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 24 (25.00%)	3 / 41 (7.32%)	
occurrences (all)	8	3	
Nasopharyngitis			
subjects affected / exposed	3 / 24 (12.50%)	0 / 41 (0.00%)	
occurrences (all)	4	0	
Tonsillitis			
subjects affected / exposed	0 / 24 (0.00%)	3 / 41 (7.32%)	
occurrences (all)	0	4	
Pneumonia			
subjects affected / exposed	3 / 24 (12.50%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 24 (8.33%)	5 / 41 (12.20%)	
occurrences (all)	3	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2022	Clarifications to exclusion criteria and study procedures

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported