



Clinical trial results:

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 1b/2a Study of WVE-003 Administered Intrathecally in Patients With Huntington's Disease

Summary

EudraCT number	2020-004556-15
Trial protocol	DE PL FR DK ES IT NL
Global end of trial date	24 June 2024

Results information

Result version number	v1 (current)
This version publication date	09 June 2025
First version publication date	09 June 2025

Trial information

Trial identification

Sponsor protocol code	WVE-003-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05032196
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Wave Life Sciences UK Limited
Sponsor organisation address	1 Chamberlain Square CS, Birmingham, United Kingdom, B33AX
Public contact	Medical Director, MD, Wave Life Sciences UK Limited, info@wavelifesci.com
Scientific contact	Medical Director, MD, Wave Life Sciences UK Limited, info@wavelifesci.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	25 June 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 May 2024
Global end of trial reached?	Yes
Global end of trial date	24 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of WVE-003 in patients with Huntington's disease (HD).

Protection of trial subjects:

The study was conducted according to the study protocol and standard operating procedures that meet the guidelines provided by the International Conference on Harmonisation for Good Clinical Practice in clinical studies, and any other applicable local regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 August 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	Netherlands: 3
Country: Number of subjects enrolled	Poland: 6
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	Canada: 10
Worldwide total number of subjects	47
EEA total number of subjects	29

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)	47
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Pts underwent prescreening to confirm they were heterozygous for SNP3 with the A variant on the same allele as the CAG triplet expansion. Prescreening was allowed to happen any time before Screening. The prescreening testing process was expected to take up to 6 weeks. If Pts met these criteria, they continued to the Screening visits.

Period 1

Period 1 title	Period 1: Single Ascending Dose
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	SAD: Pooled Placebo

Arm description:

SAD: Single dose of placebo.

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

Dosage and administration details:

20mL of placebo for intrathecal injection.

Arm title	SAD: 30mg WVE-003
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Arm description:

SAD: Single ascending dose of 30mg WVE-003. 1 Pt was randomized to WVE-003 60mg SAD group but received 30mg instead. This Pt is counted in the 30mg arm .

Arm type	Experimental
Investigational medicinal product name	WVE-003
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intrathecal use

Dosage and administration details:

20mL of 30mg WVE-003 for intrathecal injection

Arm title	SAD: 60mg WVE-003
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Arm description:

SAD: Single ascending dose of 60mg WVE-003.

Arm type	Experimental
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Investigational medicinal product name	WVE-003
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intrathecal use
Dosage and administration details: 20mL of 60mg WVE-003 for intrathecal injection.	
Arm title	SAD: 90mg WVE-003

Arm description:

SAD: Single ascending dose of 90mg WVE-003.

Arm type	Experimental
Investigational medicinal product name	WVE-003
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intrathecal use

Dosage and administration details:

20mL of 90mg WVE-003 for intrathecal injection.

Number of subjects in period 1	SAD: Pooled Placebo	SAD: 30mg WVE-003	SAD: 60mg WVE-003
Started	16	13	10
Completed	16	12	10
Not completed	0	1	0
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-

Number of subjects in period 1	SAD: 90mg WVE-003
Started	8
Completed	7
Not completed	1
Physician decision	-
Adverse event, non-fatal	1

Period 2

Period 2 title	Period 2: Multiple Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	MD: Placebo
Arm description: MD: 3 doses of placebo once every 8 weeks (Q8W). 7 Pts from Period 1 rolled over into Period 2.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intrathecal use
Dosage and administration details: 20mL placebo for 3 intrathecal injections Q8W	
Arm title	MD: 30mg WVE-003
Arm description: MD: 3 doses of 30mg WVE-003 Q8W. 16 Pts rolled over from Period 1 into Period 2.	
Arm type	Experimental
Investigational medicinal product name	WVE-003
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intrathecal use
Dosage and administration details: 20mL of 30mg WVE-003 for 3 intrathecal injection Q8W	

Number of subjects in period 2^[1]	MD: Placebo	MD: 30mg WVE-003
Started	7	16
Completed	6	16
Not completed	1	0
Physician decision	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: In this study, the number of subjects starting Period 2 is lower than the number of subjects completing Period 1, as per protocol.

Baseline characteristics

Reporting groups

Reporting group title	SAD: Pooled Placebo
Reporting group description:	
SAD: Single dose of placebo.	
Reporting group title	SAD: 30mg WVE-003
Reporting group description:	
SAD: Single ascending dose of 30mg WVE-003. 1 Pt was randomized to WVE-003 60mg SAD group but received 30mg instead. This Pt is counted in the 30mg arm .	
Reporting group title	SAD: 60mg WVE-003
Reporting group description:	
SAD: Single ascending dose of 60mg WVE-003.	
Reporting group title	SAD: 90mg WVE-003
Reporting group description:	
SAD: Single ascending dose of 90mg WVE-003.	

Reporting group values	SAD: Pooled Placebo	SAD: 30mg WVE-003	SAD: 60mg WVE-003
Number of subjects	16	13	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	13	10
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	45.5	47.8	43.9
standard deviation	± 7.4	± 9.2	± 8.6
Gender categorical			
Units: Subjects			
Female	6	6	3
Male	10	7	7
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	15	13	10
Unknown or not reported	0	0	0
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	16	13	10
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	SAD: 90mg WVE-003	Total	
Number of subjects	8	47	
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)	8	47	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	49.6		
standard deviation	± 5.3	-	
Gender categorical Units: Subjects			
Female	3	18	
Male	5	29	
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	8	46	
Unknown or not reported	0	0	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	8	47	
More than one race	0	0	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	SAD: Pooled Placebo
Reporting group description: SAD: Single dose of placebo.	
Reporting group title	SAD: 30mg WVE-003
Reporting group description: SAD: Single ascending dose of 30mg WVE-003. 1 Pt was randomized to WVE-003 60mg SAD group but received 30mg instead. This Pt is counted in the 30mg arm .	
Reporting group title	SAD: 60mg WVE-003
Reporting group description: SAD: Single ascending dose of 60mg WVE-003.	
Reporting group title	SAD: 90mg WVE-003
Reporting group description: SAD: Single ascending dose of 90mg WVE-003.	
Reporting group title	MD: Placebo
Reporting group description: MD: 3 doses of placebo once every 8 weeks (Q8W). 7 Pts from Period 1 rolled over into Period 2.	
Reporting group title	MD: 30mg WVE-003
Reporting group description: MD: 3 doses of 30mg WVE-003 Q8W. 16 Pts rolled over from Period 1 into Period 2.	

Primary: Primary: Safety: Proportion of Patients With Treatment-Emergent Adverse Events (TEAEs) related to study drug

End point title	Primary: Safety: Proportion of Patients With Treatment-Emergent Adverse Events (TEAEs) related to study drug ^[1]
End point description: Proportion of Patients with Treatment Emergent Adverse Events (TEAEs) related to study drug.	
End point type	Primary
End point timeframe: Day 1 through Week 24 (single ascending dose Period 1); Day 1 through Week 28 (multi dose Period 2)	

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: The primary endpoint of this study was safety, and as per protocol, the safety analysis was performed descriptively.

End point values	SAD: Pooled Placebo	SAD: 30mg WVE-003	SAD: 60mg WVE-003	SAD: 90mg WVE-003
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	13	10	8
Units: N Participants	2	1	3	3

End point values	MD: Placebo	MD: 30mg WVE-003		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	16		

Units: N Participants	0	8		
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Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of WVE-003 in Plasma - AUC0-6

End point title	Pharmacokinetics of WVE-003 in Plasma - AUC0-6 ^[2]
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End point description:

AUC0-6 = area under the concentration-time curve from time 0 to 6 hrs

End point type	Secondary
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End point timeframe:

Day 1 (single ascending dose Period 1); Day 1 and Day 113 (multi dose Period 2)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since these endpoints consist of pharmacokinetic analysis measuring levels of WVE-003 product, the analyses performed on placebo were done only to confirm no WVE-003 was present in these samples.

End point values	SAD: 30mg WVE-003	SAD: 60mg WVE-003	SAD: 90mg WVE-003	MD: 30mg WVE-003
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	10	8	16
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
Day 1	1000 (± 702)	2310 (± 3090)	3890 (± 2900)	822 (± 409)
Day 113	0 (± 0)	0 (± 0)	0 (± 0)	698 (± 432)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of WVE-003 in Plasma - Cmax

End point title	Pharmacokinetics of WVE-003 in Plasma - Cmax ^[3]
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End point description:

Cmax = maximum observed concentration.

End point type	Secondary
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End point timeframe:

Day 1 (single ascending dose Period 1); Day 1 and Day 113 (multi dose Period 2)

Notes:

[3] - 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: Since these endpoints consist of pharmacokinetic analysis measuring levels of WVE-003 product, the analyses performed on placebo were done only to confirm no WVE-003 was present in these samples.

End point values	SAD: 30mg WVE-003	SAD: 60mg WVE-003	SAD: 90mg WVE-003	MD: 30mg WVE-003
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	10	8	16
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	240 (± 168)	601 (± 774)	1061 (± 942)	186 (± 106)
Day 113	0 (± 0)	0 (± 0)	0 (± 0)	157 (± 97.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of WVE-003 in cerebrospinal fluid (CSF)

End point title	Concentration of WVE-003 in cerebrospinal fluid (CSF) ^[4]
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End point description:

WVE-003 concentration in cerebrospinal fluid (CSF) is reported in ng/mL.

End point type	Secondary
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End point timeframe:

28 days post-dose during Period 1 (P1:Day29); 28 days post last dose during Period 2 (P2: Day141)

Notes:

[4] - 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: Since these endpoints consist of pharmacokinetic analysis measuring levels of WVE-003 product, the analyses performed on placebo were done only to confirm no WVE-003 was present in these samples.

End point values	SAD: 30mg WVE-003	SAD: 60mg WVE-003	SAD: 90mg WVE-003	MD: 30mg WVE-003
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	10	8	16
Units: ng/mL				
arithmetic mean (standard deviation)	3.6405 (± 1.6133)	5.5346 (± 2.8402)	7.0983 (± 3.1335)	4.2903 (± 1.9722)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 through Week 24 (single ascending dose Period 1); Day 1 through Week 52 (multi dose Period 2)

Adverse event reporting additional description:

5 months after a patient completed their final safety visit, an SAE was reported that sponsor assessed to be not-related to WVE-003.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	SAD: Pooled Placebo
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Reporting group description:

SAD: Single dose of placebo.

Reporting group title	SAD: 30mg WVE-003
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Reporting group description:

SAD: 30mg WVE-003: Single ascending dose of 30mg WVE-003, an allele-selective stereopure antisense oligonucleotide (ASO)

Reporting group title	SAD: 60mg WVE-003
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Reporting group description:

SAD: 60mg WVE-003: Single ascending dose of 60mg WVE-003, an allele-selective stereopure antisense oligonucleotide (ASO)

Reporting group title	SAD: 90mg WVE-003
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Reporting group description:

SAD: 90mg WVE-003: Single ascending dose of 90mg WVE-003, an allele-selective stereopure antisense oligonucleotide (ASO)

Reporting group title	MD: Placebo
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Reporting group description:

MD: Three doses of placebo Q8W

Reporting group title	MD: 30mg WVE-003
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Reporting group description:

MD: 30mg WVE-003: Three doses of 30mg WVE-003 Q8W, an allele-selective stereopure antisense oligonucleotide (ASO)

Serious adverse events	SAD: Pooled Placebo	SAD: 30mg WVE-003	SAD: 60mg WVE-003
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 10 (10.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post lumbar puncture syndrome			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (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
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SAD: 90mg WVE-003	MD: Placebo	MD: 30mg WVE-003
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	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	SAD: Pooled Placebo	SAD: 30mg WVE-003	SAD: 60mg WVE-003
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 16 (81.25%)	9 / 13 (69.23%)	8 / 10 (80.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Haematoma			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	0 / 10 (0.00%)
occurrences (all)	3	2	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Puncture site pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Nasal congestion subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Attention deficit hyperactivity disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Compulsions subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Depressed mood subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Disorientation subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Sleep disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
CSF protein increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
CSF red blood cell count positive			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Head injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lip injury			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Post lumbar puncture syndrome			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	1 / 10 (10.00%)
occurrences (all)	2	4	1
Procedural complication			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Road traffic accident			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Upper limb fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
CSF white blood cell count increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Coordination abnormal			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Dyskinesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	6 / 16 (37.50%)	4 / 13 (30.77%)	2 / 10 (20.00%)
occurrences (all)	14	5	2
Hyperaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyporeflexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Intracranial hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Paresis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pleocytosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Tension headache			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Blood and lymphatic system disorders Eosinophilia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Eye disorders Eye pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Dental caries subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Diarrhoea subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis contact subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Eczema			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Rash			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Rash erythematous			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Skin irritation			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Back pain			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	3 / 13 (23.08%) 4	2 / 10 (20.00%) 3
Muscle contracture			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0
Musculoskeletal chest pain			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Myalgia			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Pain in extremity			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 13 (15.38%) 2	0 / 10 (0.00%) 0
Infections and infestations			
COVID-19			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1
Infected seroma			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	SAD: 90mg WVE-003	MD: Placebo	MD: 30mg WVE-003
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	7 / 7 (100.00%)	13 / 16 (81.25%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	1 / 7 (14.29%)	2 / 16 (12.50%)
occurrences (all)	1	4	7

Influenza like illness subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	1 / 16 (6.25%) 1
Pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0	2 / 16 (12.50%) 5
Puncture site pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Vessel puncture site haematoma subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Reproductive system and breast disorders Amenorrhoea subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	1 / 16 (6.25%) 1
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Compulsions			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 8 (12.50%)	1 / 7 (14.29%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Disorientation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 7 (14.29%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
CSF protein increased			

subjects affected / exposed	2 / 8 (25.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
CSF red blood cell count positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Eye injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	3 / 8 (37.50%)	2 / 7 (28.57%)	2 / 16 (12.50%)
occurrences (all)	4	4	2
Head injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Post lumbar puncture syndrome			
subjects affected / exposed	2 / 8 (25.00%)	1 / 7 (14.29%)	0 / 16 (0.00%)
occurrences (all)	6	1	0
Procedural complication			

subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 7 (14.29%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Road traffic accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Upper limb fracture			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
CSF white blood cell count increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 7 (0.00%)	2 / 16 (12.50%)
occurrences (all)	2	0	2
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	5	0	3
Coordination abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	3
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dyskinesia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	4 / 8 (50.00%)	3 / 7 (42.86%)	4 / 16 (25.00%)
occurrences (all)	7	4	5
Hyperaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyporeflexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Intracranial hypotension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 7 (14.29%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Paresis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Pleocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1

Eye disorders			
Eye pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 8 (25.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 7 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Skin irritation subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	1 / 16 (6.25%) 2
Back pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	2 / 7 (28.57%) 2	0 / 16 (0.00%) 0
Muscle contracture subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Infected seroma subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1	0 / 16 (0.00%) 0
Nasopharyngitis			

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1	2 / 16 (12.50%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1	0 / 16 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	1 / 7 (14.29%) 1	1 / 16 (6.25%) 1
Metabolism and nutrition disorders Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1	0 / 16 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2021	Amendment 1, version 2: updated protocol with modified Period 2 stopping criteria, clarified timing of effective contraception, minor exclusion criteria, and language regarding specific guidance to Investigators on disposition and follow-up of participants experiencing severe and/or serious laboratory abnormalities.
06 September 2022	Amendment 2, version 3: updated to clarify endpoints
26 September 2022	Amendment 4, version 5: Amendment 3 not implemented but changes therein were contained in Amendment 4 (Updated to further clarify endpoints, clarified that the number of cohorts and participant numbers may be modified as per DEC/SMC recommendation. Clarified participant completion required in Period 1 to be eligible for Period 2.). Updated study design for Period 2 cohort, based on data and enrollment in Period 1. Clarified that the follow-up of up to 24 weeks post-dose.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported