



Clinical trial results:

KAND567 Versus Placebo in Subjects Hospitalized with COVID-19. A Phase II, Randomized, 2-Arm Parallel-Group, Double-blind Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2020-002322-85 |
| Trial protocol | SE DK |
| Global end of trial date | 07 August 2021 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 02 July 2022 |
| First version publication date | 02 July 2022 |

Trial information

Trial identification

| | |
|-----------------------|---------|
| Sponsor protocol code | KAN0006 |
|-----------------------|---------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Kancera AB |
| Sponsor organisation address | Karolinska Institutet Science Park, Nanna Svartz Väg 4, Solna, Sweden, SE-171 65 |
| Public contact | Niclas Brynne, PhD, Kancera AB, +46 (0)8 50 12 60 80, niclas.brynne@kancera.com |
| Scientific contact | Niclas Brynne, PhD, Kancera AB, +46 (0)8 50 12 60 80, niclas.brynne@kancera.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 | 07 August 2021 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 07 August 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 August 2021 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to assess the impact of oral administration of KAND567 versus placebo, in COVID-19 subjects admitted to the hospital for care of COVID-19 infection with respect to rates of adverse events (AEs) and serious adverse events (SAEs).

Protection of trial subjects:

The external Safety Review Committee (SRC) consisted of 3 members representing appropriate clinical expertise and having extensive experience in clinical study design and conduct. No formal statistical interim analysis was to be performed, but the SRC was to evaluate all available efficacy and safety data after 10 and 20 patients had completed the 7 day treatment period. Based on this evaluation, the SRC was to give a recommendation either to continue as planned, modify the study design, or stop the study prematurely. Their recommendation was to be discussed and agreed with the Sponsor's CMO, who was responsible for making the ultimate decision.

SRC meetings consisted of an open session, based on the fully blinded dataset, to discuss general study issues. This was followed by the closed portion of the meeting, for SRC members only, to discuss the unblinded dataset (produced by an independent external programmer).

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 11 October 2020 |
| 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 | Sweden: 34 |
| Country: Number of subjects enrolled | Denmark: 1 |
| Worldwide total number of subjects | 35 |
| EEA total number of subjects | 35 |

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) | 32 |
| From 65 to 84 years | 3 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

COVID-19 patients admitted to the hospital received Best Supportive Care and could be screened for inclusion in the study. If all the criteria for study participation were fulfilled and informed consent was signed, the subject was enrolled and randomized to one of the two treatment arms.

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, Monitor, Carer |

Blinding implementation details:

The placebo was identical in appearance to KAND567, and the site staff, sponsor and CRO were blinded throughout the study. The staff at Tamro (responsible for labeling) and the staff at Q&Q Labs AB (responsible for bioanalysis) were unblinded. The independent Safety Review Committee (SRC) was also unblinded during the closed portion of their meetings, which was supported by the external, unblinded programmer who produced the dataset.

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | KAND567 (250 mg BID) |

Arm description:

KAND567 (250 mg) was orally administered every 12 hours (at 8am and 8pm \pm 1 hour) with an initial loading dose of either 250 mg or 500 mg KAND567, depending on the time of inclusion (see below).

The initial loading dose of KAND567 was given as follows:

- 500 mg was given to patients when included in the study 12 to 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)
- 250 mg was given to patients when included in the study less than 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | KAND567 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

KAND567 (250 mg) was orally administered every 12 hours (at 8am and 8pm \pm 1 hour) with an initial loading dose of either 250 mg or 500 mg KAND567, depending on the time of inclusion (see below).

The initial loading dose of KAND567 was given as follows:

- 500 mg was given to patients when included in the study 12 to 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)
- 250 mg was given to patients when included in the study less than 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Placebo was orally administered every 12 hours (at 8am and 8pm \pm 1 hour)

| | |
|----------|---------|
| Arm type | Placebo |
|----------|---------|

| | |
|--|----------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo was orally administered every 12 hours (at 8am and 8pm \pm 1 hour)

| Number of subjects in period 1 | KAND567 (250 mg BID) | Placebo |
|---------------------------------------|----------------------|---------|
| Started | 16 | 19 |
| Completed | 12 | 16 |
| Not completed | 4 | 3 |
| Adverse event, serious fatal | 1 | - |
| Consent withdrawn by subject | 3 | 3 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | KAND567 (250 mg BID) |
|-----------------------|----------------------|

Reporting group description:

KAND567 (250 mg) was orally administered every 12 hours (at 8am and 8pm \pm 1 hour) with an initial loading dose of either 250 mg or 500 mg KAND567, depending on the time of inclusion (see below).

The initial loading dose of KAND567 was given as follows:

- 500 mg was given to patients when included in the study 12 to 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)
- 250 mg was given to patients when included in the study less than 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo was orally administered every 12 hours (at 8am and 8pm \pm 1 hour)

| Reporting group values | KAND567 (250 mg BID) | Placebo | Total |
|--|----------------------|---------|-------|
| Number of subjects | 16 | 19 | 35 |
| 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) | 14 | 18 | 32 |
| From 65-84 years | 2 | 1 | 3 |
| 85 years and over | 0 | 0 | 0 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 5 | 7 | 12 |
| Male | 11 | 12 | 23 |

Subject analysis sets

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | KAND567 (Safety Analysis Set) |
|----------------------------|-------------------------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Randomized subjects who received any dose of KAND567 and for whom any post-dose data were available. Subjects were to be analyzed according to the treatment they actually received.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | Placebo (Safety Analysis Set) |
|----------------------------|-------------------------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Randomized subjects who received any dose of placebo and for whom any post-dose data were available. Subjects were to be analyzed according to the treatment they actually received.

| Reporting group values | KAND567 (Safety Analysis Set) | Placebo (Safety Analysis Set) | |
|---|-------------------------------|-------------------------------|--|
| Number of subjects | 15 | 18 | |
| 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) | 13 | 18 | |
| From 65-84 years | 2 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender categorical Units: Subjects | | | |
| Female | 5 | 7 | |
| Male | 10 | 11 | |

End points

End points reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | KAND567 (250 mg BID) |
|-----------------------|----------------------|

Reporting group description:

KAND567 (250 mg) was orally administered every 12 hours (at 8am and 8pm \pm 1 hour) with an initial loading dose of either 250 mg or 500 mg KAND567, depending on the time of inclusion (see below).

The initial loading dose of KAND567 was given as follows:

- 500 mg was given to patients when included in the study 12 to 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)
- 250 mg was given to patients when included in the study less than 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo was orally administered every 12 hours (at 8am and 8pm \pm 1 hour)

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | KAND567 (Safety Analysis Set) |
|----------------------------|-------------------------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Randomized subjects who received any dose of KAND567 and for whom any post-dose data were available. Subjects were to be analyzed according to the treatment they actually received.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | Placebo (Safety Analysis Set) |
|----------------------------|-------------------------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Randomized subjects who received any dose of placebo and for whom any post-dose data were available. Subjects were to be analyzed according to the treatment they actually received.

Primary: Number of Adverse Events

| | |
|-----------------|---|
| End point title | Number of Adverse Events ^[1] |
|-----------------|---|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

The AE reporting period started at the first administration of IMP and ended at the last FU visit.

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: No statistical analyses were performed for this endpoint.

| End point values | KAND567 (Safety Analysis Set) | Placebo (Safety Analysis Set) | | |
|-----------------------------|-------------------------------------|----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 15 | 18 | | |
| Units: occurrences | 71 | 70 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Serious Adverse Events

| | |
|-----------------|---|
| End point title | Number of Serious Adverse Events ^[2] |
|-----------------|---|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

The AE reporting period started at the first administration of IMP and ended at the last follow-up visit.

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: No statistical analyses were performed for this endpoint.

| End point values | KAND567 (Safety Analysis Set) | Placebo (Safety Analysis Set) | | |
|-----------------------------|-------------------------------------|----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 15 | 18 | | |
| Units: occurrences | 5 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The AE reporting period started at the first administration of IMP and ended at the last follow-up visit.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 23.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | KAND567 |
|-----------------------|---------|

Reporting group description:

KAND567 (250 mg) was orally administered every 12 hours (at 8am and 8pm \pm 1 hour) with an initial loading dose of either 250 mg or 500 mg KAND567, depending on the time of inclusion (see below).

The initial loading dose of KAND567 was given as follows:

- 500 mg was given to patients when included in the study 12 to 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)
- 250 mg was given to patients when included in the study less than 6 hours prior to a scheduled dose (at 8 am or 8 pm \pm 1 hour)

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo was orally administered every 12 hours (at 8am and 8pm \pm 1 hour)

| Serious adverse events | KAND567 | Placebo | |
|---|-----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 15 (33.33%) | 2 / 18 (11.11%) | |
| number of deaths (all causes) | 1 | 0 | |
| number of deaths resulting from adverse events | 1 | 0 | |
| Investigations | | | |
| Myocardial strain | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 3 / 15 (20.00%) | 0 / 18 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypoxia | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 18 (5.56%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | KAND567 | Placebo | |
|--|-------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 15 / 15 (100.00%) | 17 / 18 (94.44%) | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| General disorders and administration site conditions | | | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Chills | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|-----------------|-----------------|--|
| Asthma subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| | | | |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| | | | |
| Hypoxia subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| | | | |
| Laryngeal pain subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| | | | |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Confusional state subjects affected / exposed occurrences (all) Mental fatigue subjects affected / exposed occurrences (all) Panic attack subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) | 1 / 18 (5.56%) | |
| | 1 | 1 | |
| | | | |
| | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| | 1 | 0 | |
| | | | |
| | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| | 0 | 1 | |
| | | | |
| Investigations Fibrin D dimer increased subjects affected / exposed occurrences (all) N-terminal prohormone brain natriuretic peptide increased subjects affected / exposed occurrences (all) Alanine aminotransferase increased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased | 4 / 15 (26.67%) | 5 / 18 (27.78%) | |
| | 4 | 5 | |
| | | | |
| | 4 / 15 (26.67%) | 3 / 18 (16.67%) | |
| | 4 | 3 | |
| | | | |
| | 1 / 15 (6.67%) | 3 / 18 (16.67%) | |
| | 1 | 3 | |
| | | | |
| | | | |
| | | | |
| | | | |

| | | |
|---|-----------------|----------------|
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 18 (5.56%) |
| occurrences (all) | 1 | 1 |
| Blood alkaline phosphate increased | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| Blood creatine phosphokinase MB increased | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 |
| Blood creatine phosphokinase increased | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 0 / 18 (0.00%) |
| occurrences (all) | 2 | 0 |
| Blood glucose increased | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| Blood lactate dehydrogenase abnormal | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) |
| occurrences (all) | 1 | 0 |
| Blood lactate dehydrogenase increased | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| Blood pressure diastolic increased | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| Blood urea increased | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| C-reactive protein increased | | |
| subjects affected / exposed | 3 / 15 (20.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 3 | 1 |
| Electrocardiogram T wave inversion | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) |
| occurrences (all) | 0 | 1 |
| Gamma-glutamyltransferase increased | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 18 (5.56%) | |
| occurrences (all) | 1 | 1 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Neutrophil count increased | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 0 / 18 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| PO2 decreased | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pulmonary arterial pressure increased | | | |
| subjects affected / exposed | 3 / 15 (20.00%) | 0 / 18 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Serum ferritin increased | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 2 / 18 (11.11%) | |
| occurrences (all) | 1 | 2 | |
| Transaminases increased | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 3 / 18 (16.67%) | |
| occurrences (all) | 2 | 3 | |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| White blood cell count increased | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 1 / 18 (5.56%) | |
| occurrences (all) | 2 | 1 | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|--|--|
| Concussion subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 0 / 18 (0.00%) 0 | |
| Cardiac disorders Pericardial effusion subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) 0 | 1 / 18 (5.56%) 1 | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) 0 1 / 15 (6.67%) 1 | 2 / 18 (11.11%) 2 0 / 18 (0.00%) 0 | |
| Blood and lymphatic system disorders Thrombocytosis subjects affected / exposed occurrences (all) Anaemia subjects affected / exposed occurrences (all) Leukocytosis subjects affected / exposed occurrences (all) Neutrophilia subjects affected / exposed occurrences (all) Thrombocytopenia subjects affected / exposed occurrences (all) | 2 / 15 (13.33%) 2 2 / 15 (13.33%) 2 2 / 15 (13.33%) 2 0 / 15 (0.00%) 0 1 / 15 (6.67%) 1 | 4 / 18 (22.22%) 4 2 / 18 (11.11%) 2 2 / 18 (11.11%) 2 1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 | |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 0 / 15 (0.00%) 0 | 1 / 18 (5.56%) 1 1 / 18 (5.56%) 1 | |

| | | | |
|---|----------------------|----------------------|--|
| Frequent bowel movements subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) 0 | 1 / 18 (5.56%) 1 | |
| Gastroesophageal reflux disease subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 0 / 18 (0.00%) 0 | |
| Glossodynia subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 0 / 18 (0.00%) 0 | |
| Nausea subjects affected / exposed occurrences (all) | 3 / 15 (20.00%) 3 | 2 / 18 (11.11%) 2 | |
| Stomatitis subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) 0 | 1 / 18 (5.56%) 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Acne subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 1 / 18 (5.56%) 1 | |
| Alopecia subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 2 / 18 (11.11%) 2 | |
| Rash subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 0 / 18 (0.00%) 0 | |
| Urticaria subjects affected / exposed occurrences (all) | 1 / 15 (6.67%) 1 | 0 / 18 (0.00%) 0 | |
| Renal and urinary disorders | | | |
| Proteinuria subjects affected / exposed occurrences (all) | 3 / 15 (20.00%) 3 | 4 / 18 (22.22%) 4 | |
| Glycosuria subjects affected / exposed occurrences (all) | 0 / 15 (0.00%) 0 | 1 / 18 (5.56%) 1 | |
| Haematuria | | | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 2 / 15 (13.33%) 2 | 0 / 18 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Muscle twitching | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Myalgia | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infections and infestations | | | |
| Erythema migrans | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 18 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 18 (5.56%) | |
| occurrences (all) | 0 | 1 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 18 (5.56%) | |
| occurrences (all) | 1 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 18 December 2020 | Sweden: Changes to inclusion/exclusion criteria, clarifications made regarding restricted medications, secondary endpoints, sampling, and treatment discontinuation, and dosing diary implemented. |
| 04 March 2021 | Denmark: Change to inclusion/exclusion criteria and the sponsor's medical representative, clarifications made regarding timing of assessments, and dosing diary implemented. |
| 31 May 2021 | Sweden: Changes to inclusion/exclusion criteria and sponsor's medical representative, and clarifications made regarding timing of assessments. |
| 29 June 2021 | Sweden: Change in the primary objective and endpoint. |
| 19 July 2021 | Denmark: Change in the primary objective and endpoint. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported