



## Clinical trial results:

**An exploratory randomized, intra-individual controlled trial of the cutaneous healing properties of Petrolatum versus the vehicle for Oleogel-S10 versus no treatment when applied topically to mechanically induced partial thickness wounds in healthy volunteers**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2019-002081-12 |
| Trial protocol           | DE             |
| Global end of trial date | 04 March 2020  |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 10 June 2021 |
| First version publication date | 10 June 2021 |

### Trial information

#### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | AHV-18-A |
|-----------------------|----------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Amryt Research Ltd  |
| Sponsor organisation address | 45 Mespil Road Dublin2, Dublin 2, Ireland, D04 W2F1   |
| Public contact               | Head of Clinical Development, Amryt Research Ltd., 353 15180200, janet.boylan@amrytpharma.com |
| Scientific contact           | Head of Clinical Development, Amryt Research Ltd., 353 15180200, janet.boylan@amrytpharma.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                       | 04 March 2020 |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 04 March 2020 |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 04 March 2020 |
| Was the trial ended prematurely?                     | No            |

Notes:

## General information about the trial

Main objective of the trial:

To describe and to measure cutaneous healing of mechanically induced wounds with application of vehicle of Oleogel-S10, petrolatum, and no treatment in healthy volunteers in a wound healing model of mechanically induced wounds.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles derived from the principles of Good Clinical Practices (GCP) and the declaration of Helsinki (1964) including all amendments up to the October 2013 revision. All local regulatory requirements pertinent to the safety of trial subjects were followed during the conduct of the trial. Patients attended daily throughout the trial and adverse events were monitored throughout the study.

Background therapy:

None

Evidence for comparator:

Topically applied leave-on products may be helpful to enhance cutaneous healing and re-epithelization of cutaneous wounds. An occlusive and 'protective' effect seems to be responsible for this phenomenon, but the performance of products depends on the overall composition and possible active ingredients. Amryt Pharma developed a vehicle of Oleogel-S10 to be used in a clinical phase III study comparing the efficacy of Oleogel-S10 to vehicle for the treatment of Epidermolysis bullosa (EB). Petrolatum is considered an example of a standard topical product to promote cutaneous healing in the management of wounds caused by EB. It is expected that the vehicle gel, that has been developed for use as a blinded comparator in the EB study, has similar beneficial effects on wound healing to those associated with the use of petrolatum.

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 23 January 2020 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | No              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Germany: 12 |
| Worldwide total number of subjects   | 12          |
| EEA total number of subjects         | 12          |

Notes:

### Subjects enrolled per age group

|  |   |
|--|---|
| In utero                               | 0 |
| Preterm newborn - gestational age < 37 | 0 |

|  |    |
|--|----|
| wk                                       |    |
| 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)                     | 12 |
| From 65 to 84 years                      | 0  |
| 85 years and over                        | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Adult healthy volunteers (n = 6 male, n = 6 female) were enrolled in the trial at the Clinical Research Center for Hair and Skin Science (CRC), Department of Dermatology and Allergy, Charité-Universitätsmedizin Berlin, Germany. The first patient first visit was 23-Jan-2020 and the last patient last visit was 04-Mar-2020.

### Pre-assignment

Screening details:

Subjects underwent assessments to determine eligibility at the Initial Screening Visit (Day-14 to Day-3). A total of 16 subjects entered the screening phase for which 12 proceeded to the recruitment.

### Period 1

|                              |                                 |
|------------------------------|---------------------------------|
| Period 1 title               | Overall period (overall period) |
| Is this the baseline period? | Yes                             |
| Allocation method            | Non-randomised - controlled     |
| Blinding used                | Not blinded                     |

Blinding implementation details:

Study personnel who administered the intervention and the subjects who received the interventions were not blinded. The Investigators and study staff who performed the wound assessments were blinded to treatment.

### Arms

|                              |             |
|------------------------------|-------------|
| Are arms mutually exclusive? | No          |
| <b>Arm title</b>             | Control Gel |

Arm description:

Treatment with Control Gel

|  |                         |
|--|-------------------------|
| Arm type                               | Experimental            |
| Investigational medicinal product name | Control Gel             |
| Investigational medicinal product code |                         |
| Other name                             | Vehicle for Oleogel-S10 |
| Pharmaceutical forms                   | Gel                     |
| Routes of administration               | Cutaneous use           |

Dosage and administration details:

Applied topically once daily for 21 days at a thickness of approximately 1 mm (0.04 inch) over the wound area (diameter 8 mm to cover the wound edges). The treated areas were covered with a non adhesive wound dressing with a non adherent pad (Mepitel®Film) from Day 1 through Day 10 immediately after product application.

|                  |                                      |
|------------------|--------------------------------------|
| <b>Arm title</b> | Petrolatum (ALLERGIKA® – BASISSALBE) |
|------------------|--------------------------------------|

Arm description:

Treatment with Petrolatum (ALLERGIKA® – BASISSALBE)

|  |                                      |
|--|--------------------------------------|
| Arm type                               | Experimental                         |
| Investigational medicinal product name | Petrolatum (ALLERGIKA® – BASISSALBE) |
| Investigational medicinal product code |                                      |
| Other name                             |                                      |
| Pharmaceutical forms                   | Gel                                  |
| Routes of administration               | Cutaneous use                        |

Dosage and administration details:

Applied topically once daily for 21 days at a thickness of approximately 1 mm (0.04 inch) over the wound area (diameter 8 mm to cover the wound edges). The treated areas were covered with a non adhesive wound dressing with a non adherent pad (Mepitel®Film) from Day 1 through Day 10 immediately after product application.

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Untreated control |
|------------------|-------------------|

Arm description:

No topical treatment applied. Covered with a non adhesive wound dressing with a non adherent pad (Mepitel®Film) from Day 1 through Day 10.

|          |                 |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

|   |
|---|
| No investigational medicinal product assigned in this arm |
|---|

| Number of subjects in period 1 | Control Gel | Petrolatum<br>(ALLERGIKA® –<br>BASISSALBE) | Untreated control |
|--------------------------------|-------------|--|-------------------|
|                                |             |  |                   |
| Started                        | 12          | 12   | 12                |
| Completed                      | 11          | 11   | 11                |
| Not completed                  | 1           | 1  | 1                 |
| Lost to follow-up              | 1           | 1  | 1                 |

## Baseline characteristics

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### Reporting groups

|                       |                |
|-----------------------|----------------|
| Reporting group title | Overall period |
|-----------------------|----------------|

Reporting group description: -

| Reporting group values | Overall period | Total |  |
|------------------------|----------------|-------|--|
| Number of subjects     | 12             | 12    |  |
| Age categorical        |                |       |  |
| Units: Subjects        |                |       |  |
| Adults (18-64 years)   | 12             | 12    |  |
| Gender categorical     |                |       |  |
| Units: Subjects        |                |       |  |
| Female                 | 6              | 6     |  |
| Male                   | 6              | 6     |  |

## End points

### End points reporting groups

|  |                                      |
|--|--------------------------------------|
| Reporting group title  | Control Gel                          |
| Reporting group description:   |                                      |
| Treatment with Control Gel   |                                      |
| Reporting group title  | Petrolatum (ALLERGIKA® – BASISSALBE) |
| Reporting group description:   |                                      |
| Treatment with Petrolatum (ALLERGIKA® – BASISSALBE)  |                                      |
| Reporting group title  | Untreated control                    |
| Reporting group description:   |                                      |
| No topical treatment applied. Covered with a non adhesive wound dressing with a non adherent pad (Mepitel®Film) from Day 1 through Day 10. |                                      |

### Primary: Complete wound healing according to Clinical Score

|   |   |
|---|---|
| End point title   | Complete wound healing according to Clinical Score <sup>[1]</sup> |
| End point description:  |   |
| A six category clinical score was used to assess the degree of epithelialisation (0=0% [no healing], 1=1 to 25% re epithelialisation, 2=26 to 50% re epithelialisation, 3=51 to 75% re-epithelialisation, 4=Greater than 75% re epithelialisation, but not complete healing, 5=100% re epithelialisation [complete healing]). |   |
| End point type  | Primary   |
| End point timeframe:  |   |
| Wound healing was assessed from Day 1 through Day 28.   |   |

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: As this was an exploratory study, only descriptive statistical methods were applied. The investigational medicinal products (IMPs) and the untreated control were not compared using a statistical test; no null hypotheses were tested.

| End point values                      | Control Gel         | Petrolatum (ALLERGIKA® – BASISSALBE) | Untreated control   |  |
|---------------------------------------|---------------------|--------------------------------------|---------------------|--|
| Subject group type                    | Reporting group     | Reporting group                      | Reporting group     |  |
| Number of subjects analysed           | 11                  | 11                                   | 11                  |  |
| Units: Days to complete wound healing |                     |                                      |                     |  |
| number (confidence interval 95%)      | 13.3 (12.3 to 14.2) | 13.4 (12.4 to 14.3)                  | 13.3 (12.3 to 14.3) |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Complete wound healing according to Planimetry

|  |   |
|--|---|
| End point title  | Complete wound healing according to Planimetry <sup>[2]</sup> |
| End point description:   |   |
| Wound healing measurements (planimetry) were performed by computerised image analysis using the software ImageJ. |   |

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

End point timeframe:

Wound healing was assessed from Day 1 through Day 28.

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: As this was an exploratory study, only descriptive statistical methods were applied. The investigational medicinal products (IMPs) and the untreated control were not compared using a statistical test; no null hypotheses were tested.

| End point values                      | Control Gel        | Petrolatum (ALLERGIKA® – BASISSALBE) | Untreated control  |  |
|---------------------------------------|--------------------|--------------------------------------|--------------------|--|
| Subject group type                    | Reporting group    | Reporting group                      | Reporting group    |  |
| Number of subjects analysed           | 11                 | 11                                   | 11                 |  |
| Units: Days to complete wound healing |                    |                                      |                    |  |
| number (confidence interval 95%)      | 10.6 (9.8 to 11.4) | 10.5 (9.6 to 11.3)                   | 10.6 (9.5 to 11.8) |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Adverse Events

|                 |                |
|-----------------|----------------|
| End point title | Adverse Events |
|-----------------|----------------|

End point description:

Incidence, severity and causality of local tolerance AEs, and incidence, severity and causality of all AEs.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Adverse events (AEs) were monitored throughout the study from the time of informed consent through Day 28.

| End point values            | Control Gel     | Petrolatum (ALLERGIKA® – BASISSALBE) | Untreated control |  |
|-----------------------------|-----------------|--------------------------------------|-------------------|--|
| Subject group type          | Reporting group | Reporting group                      | Reporting group   |  |
| Number of subjects analysed | 12              | 12                                   | 12                |  |
| Units: Adverse Events       |                 |                                      |                   |  |
| Medical device site papule  | 7               | 7                                    | 7                 |  |
| Application site papules    | 4               | 1                                    | 2                 |  |
| Medical device site pustule | 1               | 1                                    | 1                 |  |
| Epistaxis                   | 1               | 1                                    | 1                 |  |
| Nasopharyngitis             | 1               | 1                                    | 1                 |  |

## Statistical analyses



No statistical analyses for this end point

### Secondary: Clinical Score Per Day

|  |                        |
|--|------------------------|
| End point title  | Clinical Score Per Day |
| End point description:<br>A six category clinical score was used to assess the degree of epithelialisation (0=0% [no healing], 1=1 to 25% re epithelialisation, 2=26 to 50% re epithelialisation, 3=51 to 75% re epithelialisation, 4=Greater than 75% re epithelialisation, but not complete healing, 5=100% re epithelialisation [complete healing]) |                        |
| End point type   | Secondary              |
| End point timeframe:<br>Wound healing was assessed from Day 1 through Day 28.  |                        |

| End point values              | Control Gel     | Petrolatum (ALLERGIKA® - BASISSALBE) | Untreated control |  |
|-------------------------------|-----------------|--------------------------------------|-------------------|--|
| Subject group type            | Reporting group | Reporting group                      | Reporting group   |  |
| Number of subjects analysed   | 11              | 11                                   | 11                |  |
| Units: Clinical Score per Day |                 |                                      |                   |  |
| median (full range (min-max)) |                 |                                      |                   |  |
| Day 2                         | 0 (0 to 1)      | 0 (0 to 0)                           | 0 (0 to 0)        |  |
| Day 3                         | 1 (0 to 1)      | 1 (0 to 1)                           | 1 (0 to 2)        |  |
| Day 4                         | 1 (1 to 1)      | 1 (1 to 1)                           | 1 (1 to 2)        |  |
| Day 5                         | 1 (1 to 2)      | 1 (1 to 2)                           | 1 (1 to 2)        |  |
| Day 6                         | 2 (1 to 4)      | 2 (1 to 3)                           | 2 (1 to 3)        |  |
| Day 7                         | 2.5 (2 to 4)    | 3 (2 to 4)                           | 3 (1 to 4)        |  |
| Day 8                         | 3 (2 to 4)      | 3.5 (2 to 4)                         | 3 (2 to 4)        |  |
| Day 9                         | 3.5 (3 to 4)    | 3.5 (3 to 4)                         | 4 (3 to 4)        |  |
| Day 10                        | 4 (3 to 4)      | 4 (3 to 4)                           | 4 (4 to 4)        |  |
| Day 11                        | 4 (4 to 5)      | 4 (3 to 5)                           | 4 (4 to 5)        |  |
| Day 12                        | 4 (4 to 5)      | 4 (4 to 5)                           | 4 (4 to 5)        |  |
| Day 13                        | 4.5 (4 to 5)    | 5 (4 to 5)                           | 4.5 (4 to 5)      |  |
| Day 14                        | 5 (4 to 5)      | 5 (4 to 5)                           | 5 (4 to 5)        |  |
| Day 15                        | 5 (5 to 5)      | 5 (4 to 5)                           | 5 (4 to 5)        |  |
| Day 16 to 28                  | 5 (5 to 5)      | 5 (5 to 5)                           | 5 (5 to 5)        |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean TEWL Per Wound

|  |                     |
|--|---------------------|
| End point title  | Mean TEWL Per Wound |
| End point description:<br>TEWL was measured according to international guidelines.               |                     |
| End point type   | Secondary           |
| End point timeframe:<br>Transepidermal water loss (TEWL) was assessed from Day 1 through Day 28. |                     |

| End point values                          | Control Gel       | Petrolatum (ALLERGIKA® – BASISSALBE) | Untreated control |  |
|---|-------------------|--------------------------------------|-------------------|--|
| Subject group type                        | Reporting group   | Reporting group                      | Reporting group   |  |
| Number of subjects analysed               | 12 <sup>[3]</sup> | 12 <sup>[4]</sup>                    | 12 <sup>[5]</sup> |  |
| Units: TEWL Per Day (g/m <sup>2</sup> /h) |                   |                                      |                   |  |
| arithmetic mean (standard deviation)      |                   |                                      |                   |  |
| Day 1                                     | 76.2 (± 9.4)      | 75.5 (± 11.0)                        | 77.4 (± 6.7)      |  |
| Day 3                                     | 73.3 (± 7.7)      | 74.6 (± 6.7)                         | 76.1 (± 4.8)      |  |
| Day 5                                     | 58.2 (± 13.4)     | 62.6 (± 12.2)                        | 60.3 (± 13.7)     |  |
| Day 7                                     | 23.7 (± 15.6)     | 26.5 (± 19.5)                        | 25.1 (± 18.4)     |  |
| Day 9                                     | 14.0 (± 13.9)     | 15.1 (± 18.0)                        | 15.5 (± 17.9)     |  |
| Day 11                                    | 9.0 (± 2.7)       | 11.2 (± 9.4)                         | 11.3 (± 8.3)      |  |
| Day 13                                    | 10.7 (± 1.9)      | 10.8 (± 2.9)                         | 12.8 (± 3.4)      |  |
| Day 15                                    | 12.8 (± 3.6)      | 11.4 (± 2.9)                         | 13.8 (± 3.9)      |  |
| Day 17                                    | 11.4 (± 3.1)      | 10.2 (± 3.2)                         | 11.5 (± 2.1)      |  |
| Day 19                                    | 10.4 (± 2.4)      | 9.0 (± 1.5)                          | 10.1 (± 1.9)      |  |
| Day 21                                    | 10.3 (± 3.3)      | 9.0 (± 1.7)                          | 9.9 (± 1.6)       |  |
| Day 23                                    | 8.8 (± 1.8)       | 8.7 (± 2.1)                          | 8.8 (± 1.6)       |  |
| Day 28                                    | 9.9 (± 2.7)       | 10.3 (± 3.0)                         | 10.0 (± 2.8)      |  |

Notes:

[3] - Day 1 to 13: N=12; Day 15 to 28: N=11

[4] - Day 1 to 13: N=12; Day 15 to 28: N=11

[5] - Day 1 to 13: N=12; Day 15 to 28: N=11

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Wound Surface Area According to Planimetry

|                 |   |
|-----------------|---|
| End point title | Mean Wound Surface Area According to Planimetry |
|-----------------|---|

End point description:

For measurement of wound area, standardised photographs of each wound were taken; at least two photographs were taken at each timepoint and the best image (after assessment for clarity and quality) was stored for subsequent image analysis. Wound healing measurements (planimetry) were performed by computerised image analysis using the software ImageJ.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Wound healing was assessed from Day 1 through Day 28.

| End point values                                     | Control Gel       | Petrolatum (ALLERGIKA® – BASISSALBE) | Untreated control |  |
|--|-------------------|--------------------------------------|-------------------|--|
| Subject group type                                   | Reporting group   | Reporting group                      | Reporting group   |  |
| Number of subjects analysed                          | 12 <sup>[6]</sup> | 12 <sup>[7]</sup>                    | 12 <sup>[8]</sup> |  |
| Units: Wound Surface Area Per Day (mm <sup>2</sup> ) |                   |                                      |                   |  |
| arithmetic mean (standard deviation)                 |                   |                                      |                   |  |

|              |              |              |              |  |
|--------------|--------------|--------------|--------------|--|
| Day 1        | 43.2 (± 8.1) | 44.2 (± 5.5) | 42.9 (± 5.8) |  |
| Day 3        | 32.3 (± 7.3) | 35.1 (± 5.8) | 34.1 (± 5.7) |  |
| Day 5        | 18.6 (± 6.2) | 19.1 (± 4.9) | 20.8 (± 8.2) |  |
| Day 7        | 8.1 (± 6.7)  | 6.6 (± 4.0)  | 7.8 (± 7.4)  |  |
| Day 9        | 1.4 (± 1.9)  | 1.9 (± 2.5)  | 4.2 (± 9.9)  |  |
| Day 11       | 0.1 (± 0.2)  | 0.4 (± 1.0)  | 0.2 (± 0.6)  |  |
| Day 13 to 28 | 0.0 (± 0.0)  | 0.0 (± 0.0)  | 0.0 (± 0.0)  |  |

Notes:

[6] - Day 1 to 9: N=12; Day 11 to 28: N=11

[7] - Day 1 to 9: N=12; Day 11 to 28: N=11

[8] - Day 1 to 9: N=12; Day 11 to 28: N=11

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were monitored throughout the study from the time of informed consent through Day 28.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 23.0   |

### Reporting groups

|                       |                                      |
|-----------------------|--------------------------------------|
| Reporting group title | Petrolatum (ALLERGIKA® – BASISSALBE) |
|-----------------------|--------------------------------------|

Reporting group description:

Treatment with Petrolatum (ALLERGIKA® – BASISSALBE)

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Untreated control |
|-----------------------|-------------------|

Reporting group description:

No topical treatment applied. Covered with a non adhesive wound dressing with a non adherent pad (Mepitel®Film) from Day 1 through Day 10.

|                       |             |
|-----------------------|-------------|
| Reporting group title | Control Gel |
|-----------------------|-------------|

Reporting group description:

Treatment with Control Gel

| <b>Serious adverse events</b>                     | Petrolatum<br>(ALLERGIKA® –<br>BASISSALBE) | Untreated control | Control Gel    |
|---|--|-------------------|----------------|
| Total subjects affected by serious adverse events |  |                   |                |
| subjects affected / exposed                       | 0 / 12 (0.00%)                             | 0 / 12 (0.00%)    | 0 / 12 (0.00%) |
| number of deaths (all causes)                     | 0  | 0                 | 0              |
| number of deaths resulting from adverse events    | 0  | 0                 | 0              |

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

| <b>Non-serious adverse events</b>                     | Petrolatum<br>(ALLERGIKA® –<br>BASISSALBE) | Untreated control | Control Gel     |
|---|--|-------------------|-----------------|
| Total subjects affected by non-serious adverse events |  |                   |                 |
| subjects affected / exposed                           | 7 / 12 (58.33%)                            | 8 / 12 (66.67%)   | 9 / 12 (75.00%) |
| General disorders and administration site conditions  |  |                   |                 |
| Medical device site papule                            |  |                   |                 |
| subjects affected / exposed                           | 6 / 12 (50.00%)                            | 6 / 12 (50.00%)   | 6 / 12 (50.00%) |
| occurrences (all)                                     | 7  | 7                 | 7               |
| Application site papules                              |  |                   |                 |

|   |  |  |  |
|---|--|--|--|
| subjects affected / exposed<br>occurrences (all)  | 1 / 12 (8.33%)<br>1                            | 2 / 12 (16.67%)<br>2                           | 4 / 12 (33.33%)<br>4                           |
| Respiratory, thoracic and mediastinal disorders<br>Epistaxis<br>subjects affected / exposed<br>occurrences (all)  | 1 / 12 (8.33%)<br>1                            | 1 / 12 (8.33%)<br>1                            | 1 / 12 (8.33%)<br>1                            |
| Infections and infestations<br>Medical device site pustule<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all) | 1 / 12 (8.33%)<br>1<br><br>1 / 12 (8.33%)<br>1 | 1 / 12 (8.33%)<br>1<br><br>1 / 12 (8.33%)<br>1 | 1 / 12 (8.33%)<br>1<br><br>1 / 12 (8.33%)<br>1 |

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported