



## Clinical trial results:

### Open-label Phase IV Study to Investigate Broad-and Cross-neutralizing Antibodies after Primary Vaccination with Two Different TBE Vaccines Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2018-004674-94 |
| Trial protocol           | LV             |
| Global end of trial date | 14 June 2024   |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 16 July 2025 |
| First version publication date | 16 July 2025 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | WI237607 |
|-----------------------|----------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |                                                                                                |
|------------------------------|------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Riga Stradiņš University                                                                       |
| Sponsor organisation address | Dzirčiema 16, Rīga, Latvia, LV-1007                                                            |
| Public contact               | Clinical Trial Information Desk, Riga Stradiņš University, +371 26494938, dace.zavadska@rsu.lv |
| Scientific contact           | Clinical Trial Information Desk, Riga Stradiņš University, +371 26494938, dace.zavadska@rsu.lv |

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                       | 05 June 2025 |
| Is this the analysis of the primary completion data? | Yes          |
| Primary completion date                              | 14 June 2024 |
| Global end of trial reached?                         | Yes          |
| Global end of trial date                             | 14 June 2024 |
| Was the trial ended prematurely?                     | No           |

Notes:

## General information about the trial

Main objective of the trial:

To describe the immune response induced by FSME-IMMUN/TicoVac or Encepur against two virus strains Neudorfl (Nd) used to manufacture FSME/IMMUN/TicoVac and mutated Karlsruhe (mk23) (one homologous strain and one heterologous strain to each vaccine), as measured by NT using an established hybrid virus assay platform.

Protection of trial subjects:

The study was conducted in full compliance with the protocol, any applicable legal and regulatory requirements, as well as with scientific purpose, value, rigor, and followed the generally accepted research practices described in the ICH Good Clinical Practice guidelines. The study was performed in full compliance with the legal regulations according to the applicable law(s) in Latvia. The protocol, protocol amendments, ICD, and other relevant documents (e.g., advertisements) were submitted to an IEC by the investigator and reviewed and approved by the IEC before the study was initiated. Any amendments to the protocol required IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants. Informed consent was obtained from all participants or their legally authorized representative prior to enrollment. Based on the very well-defined safety profile of both vaccines, only SAEs occurring from administration of the first vaccination through 28 calendar days after the second vaccination and from administration of the third vaccination through 28 calendar days thereafter were collected. If the Investigator became aware of an SAE after the 28-day period and suspected a causal relationship between the vaccine and the SAE, this was also to be reported. Protocol deviations were identified and managed throughout the study by monitoring of informed consent documentation, source documents, and other clinical trial-related documents. In addition, protocol deviations were identified by CRF review and programmatically from the clinical trial database

Background therapy: -

Evidence for comparator: -

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 11 April 2019 |
| 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 | Latvia: 438 |
| Worldwide total number of subjects   | 438         |
| EEA total number of subjects         | 438         |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 19  |
| Children (2-11 years)                     | 90  |
| Adolescents (12-17 years)                 | 108 |
| Adults (18-64 years)                      | 147 |
| From 65 to 84 years                       | 74  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Participant recruitment was conducted at three locations in Latvia - Children's Clinical University Hospital, RSU Ambulance, and GK Neuroclinic. Recruitment period was from April 11, 2019 till June 3, 2020.

### Pre-assignment

Screening details:

Participants were screened based on strict criteria. Inclusion required healthy individuals aged  $\geq 1$  year, with informed consent/assent and protocol compliance. Exclusion included prior TBE vaccination, flavivirus exposure, contraindications to TBE vaccine, pregnancy, immunosuppression and other conditions according to protocol.

### Period 1

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

Blinding implementation details:

No blinding was implemented. Both investigators and participants were aware of the assigned vaccine—either FSME-IMMUN/TicoVac or Encepur—administered according to age-appropriate dosing schedules. Blinding was not considered necessary due to the study's primary focus on immunogenicity

### Arms

|                              |                  |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes              |
| <b>Arm title</b>             | FSME-IMMUN Group |

Arm description:

Arm 1 of the study involved participants receiving three age-appropriate doses of the FSME-IMMUN (TicoVac) vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Neudörfl (Nd) strain.

|                                        |                                                |
|----------------------------------------|------------------------------------------------|
| Arm type                               | Active treatment                               |
| Investigational medicinal product name | FSME-IMMUN vaccine                             |
| Investigational medicinal product code |                                                |
| Other name                             | TicoVac                                        |
| Pharmaceutical forms                   | Suspension for injection in pre-filled syringe |
| Routes of administration               | Intramuscular use                              |

Dosage and administration details:

Subjects were vaccinated on Day 0, at 1 month, and then 9-10 months later, following the standard FSME-IMMUN schedule. The vaccine was administered via intramuscular (IM) injection, with a dose volume of 0.25 mL for children aged 1–15 years (pediatric formulation) and 0.5 mL for individuals aged 16 years and older (adult formulation).

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | ENCEPUR group |
|------------------|---------------|

Arm description:

Arm 2 of the study involved participants receiving three age-appropriate doses of the Encepur vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Karlsruhe (mK23) strain.

|                                        |                                                |
|----------------------------------------|------------------------------------------------|
| Arm type                               | Active treatment                               |
| Investigational medicinal product name | Encepur vaccine                                |
| Investigational medicinal product code |                                                |
| Other name                             |                                                |
| Pharmaceutical forms                   | Suspension for injection in pre-filled syringe |
| Routes of administration               | Intramuscular use                              |

Dosage and administration details:

Subjects were vaccinated on Day 0, at 1 month, and then 9–12 months later, following the standard Encepur schedule. The vaccine was administered via intramuscular (IM) injection, with a dose volume of

0.25 mL for children aged 1–11 years (pediatric formulation) and 0.5 mL for individuals aged 12 years and older (adult formulation).

| <b>Number of subjects in period 1</b>    | FSME-IMMUN Group | ENCEPUR group |
|------------------------------------------|------------------|---------------|
| Started                                  | 219              | 219           |
| Randomized                               | 219              | 219           |
| Vaccinated - Dose 1                      | 218              | 218           |
| Vaccinated - Dose 2                      | 214              | 212           |
| Vaccinated - Dose 3                      | 210              | 202           |
| Vaccination phase (Completed Visits 1-5) | 208              | 195           |
| Seropersistence phase (Visits 6-8)       | 165              | 155           |
| Completed                                | 165              | 155           |
| Not completed                            | 54               | 64            |
| Consent withdrawn by subject             | 40               | 36            |
| Physician decision                       | 6                | 8             |
| Lost to follow-up                        | 8                | 20            |

## Baseline characteristics

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | FSME-IMMUN Group |
|-----------------------|------------------|

Reporting group description:

Arm 1 of the study involved participants receiving three age-appropriate doses of the FSME-IMMUN (TicoVac) vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Neudörfl (Nd) strain.

|                       |               |
|-----------------------|---------------|
| Reporting group title | ENCEPUR group |
|-----------------------|---------------|

Reporting group description:

Arm 2 of the study involved participants receiving three age-appropriate doses of the Encepur vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Karlsruhe (mK23) strain.

| Reporting group values                                                                                                | FSME-IMMUN Group | ENCEPUR group | Total |
|-----------------------------------------------------------------------------------------------------------------------|------------------|---------------|-------|
| Number of subjects                                                                                                    | 219              | 219           | 438   |
| Age categorical                                                                                                       |                  |               |       |
| Subjects were stratified evenly across four age groups: 1–11 years, 12–15 years, 16–59 years, and 60 years and older. |                  |               |       |
| Units: Subjects                                                                                                       |                  |               |       |
| 1–11 years                                                                                                            | 54               | 55            | 109   |
| 12–15 years                                                                                                           | 52               | 53            | 105   |
| 16–59 years                                                                                                           | 53               | 53            | 106   |
| 60 years and older                                                                                                    | 60               | 58            | 118   |
| Gender categorical                                                                                                    |                  |               |       |
| Units: Subjects                                                                                                       |                  |               |       |
| Female                                                                                                                | 129              | 131           | 260   |
| Male                                                                                                                  | 90               | 88            | 178   |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                       | FSME-IMMUN Group                                              |
| Reporting group description:<br>Arm 1 of the study involved participants receiving three age-appropriate doses of the FSME-IMMUN (TicoVac) vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Neudörfl (Nd) strain.                                                                                                                                                                                                                     |                                                               |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ENCEPUR group                                                 |
| Reporting group description:<br>Arm 2 of the study involved participants receiving three age-appropriate doses of the Encepur vaccine, an inactivated whole-virus tick-borne encephalitis (TBE) vaccine based on the Karlsruhe (mK23) strain.                                                                                                                                                                                                                               |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Randomized (ITT Population)                                   |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Intention-to-treat                                            |
| Subject analysis set description:<br>The randomized ITT population refers to all 438 participants who were randomized into the study, regardless of whether they actually received the vaccine or completed the study as per protocol.                                                                                                                                                                                                                                      |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Modified ITT population                                       |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Modified intention-to-treat                                   |
| Subject analysis set description:<br>The Modified Intent-to-Treat (mITT) population included 436 subjects. mITT is a refined subset of the randomized participants used for more targeted immunogenicity analyses, it includes all participants who received at least one dose of the study vaccine and had at least one postvaccination blood sample with a valid and determinate assay result.                                                                            |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Postdose 2 Per-Protocol Immunogenicity Population             |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                                  |
| Subject analysis set description:<br>Postdose 2 Per-Protocol Immunogenicity Population included 362 subjects. Of them, 187 subjects enrolled in Schedule A Dose 2 (6-Day Postdose 2 Per-Protocol Immunogenicity Population), which consisted of FSME-IMMUN group N=100 and ENCEPUR group N=87. And 175 subjects enrolled in Schedule B Dose 2 (1-Month Postdose 2 Per-Protocol Immunogenicity Population), which consisted of FSME-IMMUN group N=88 and ENCEPUR group N=87. |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Predose 3 Per-Protocol Immunogenicity Population              |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                                  |
| Subject analysis set description:<br>Predose 3 Per-Protocol Immunogenicity Population included 362 subjects. Of them, FSME-IMMUN group N=190, ENCEPUR group N=172.                                                                                                                                                                                                                                                                                                          |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Postdose 3 Per-Protocol Immunogenicity Population             |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                                  |
| Subject analysis set description:<br>Postdose 3 Per-Protocol Immunogenicity Population included 343 subjects. Of them, 164 subjects enrolled in Schedule A Dose 3 (6-Day Postdose 3 Per-Protocol Immunogenicity Population), which consisted of FSME-IMMUN group N=88 and ENCEPUR group N=76. And 179 subjects enrolled in Schedule B Dose 3 (1-Month Postdose 3 Per-Protocol Immunogenicity Population), which consisted of FSME-IMMUN group N=94 and ENCEPUR group N=85.  |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1-Year Seropersistence Postdose 3 Per Protocol Immunogenicity |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                                  |
| Subject analysis set description:<br>1-Year Seropersistence Postdose 3 Per Protocol Immunogenicity included 334 subjects, of them FSME-IMMUN group N=179; ENCEPUR group N=155.                                                                                                                                                                                                                                                                                              |                                                               |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 2-Year Seropersistence Postdose 3 Per Protocol Immunogenicity |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                                  |
| Subject analysis set description:<br>2-Year Seropersistence Postdose 3 Per Protocol Immunogenicity Population included 301 subject, of                                                                                                                                                                                                                                                                                                                                      |                                                               |

them FSME-IMMUN group N=157, ENCEPUR group N=144.

|                                                                                                                                                      |                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Subject analysis set title                                                                                                                           | 3-Year Seropersistence Postdose 3 Per Protocol Immunogenicity |
| Subject analysis set type                                                                                                                            | Per protocol                                                  |
| Subject analysis set description:                                                                                                                    |                                                               |
| 3-Year Seropersistence Postdose 3 Per Protocol Immunogenicity Population included 278 subjects, of them FSME-IMMUN group N=147, ENCEPUR group N=131. |                                                               |

### Primary: Subjects Achieving NT $\geq$ 7.7 and Composite Response – FSME-IMMUN Per-Protocol Immunogenicity Populations

|                 |                                                                                                                                |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|
| End point title | Subjects Achieving NT $\geq$ 7.7 and Composite Response – FSME-IMMUN Per-Protocol Immunogenicity Populations <sup>[1][2]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|

End point description:

The proportion of composite response of neutralizing titers against both homologous and heterologous antigens to the vaccines (FSME-IMMUN) at each blood draw visit. The composite response is defined as a subject with NT $\geq$ 7.7 for both Nd and mK23.

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

End point timeframe:

Blood draws for the investigation of the humoral immune response were performed prior to the first vaccination (FSME-IMMUN); after Dose 2; prior and after Dose 3; and for the 1-year, 2-year and 3-year post-Dose 3.

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: This was a descriptive study not powered to show superiority/ non-inferiority of any product. No formal hypothesis testing or statistical comparisons were pre-specified or conducted for the primary endpoint.

[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: This was a descriptive study not powered to show superiority/ non-inferiority of any product. Encepur group results are reported as separate primary endpoint.

| End point values                       | FSME-IMMUN Group   |  |  |  |
|----------------------------------------|--------------------|--|--|--|
| Subject group type                     | Reporting group    |  |  |  |
| Number of subjects analysed            | 218 <sup>[3]</sup> |  |  |  |
| Units: %                               |                    |  |  |  |
| 6-Day Postdose 2 Per-Protocol (N=100)  | 87                 |  |  |  |
| 1-Month Postdose 2 Per-Protocol (N=88) | 89                 |  |  |  |
| Predose 3 Per-Protocol (N=190)         | 37                 |  |  |  |
| 6-Day Postdose 3 Per-Protocol (N=88)   | 75                 |  |  |  |
| 1-Month Postdose 3 Per-Protocol (N=94) | 96                 |  |  |  |
| 1-Year Postdose 3 Per-Protocol (N=179) | 82                 |  |  |  |
| 2-Year Postdose 3 Per-Protocol (N=157) | 87                 |  |  |  |
| 3-Year Postdose 3 Per-Protocol (N=147) | 80                 |  |  |  |

Notes:

[3] - Total number of subjects vaccinated with FSME-IMMUN.

### Statistical analyses

No statistical analyses for this end point

### Primary: Subjects Achieving NT $\geq$ 7.7 and Composite Response – Encepur Per-Protocol Immunogenicity Populations

|                 |                                                           |
|-----------------|-----------------------------------------------------------|
| End point title | Subjects Achieving NT $\geq$ 7.7 and Composite Response – |
|-----------------|-----------------------------------------------------------|

**End point description:**

The proportion of composite response of neutralizing titers against both homologous and heterologous antigens to the vaccines (Encepur) at each blood draw visit. The composite response is defined as a subject with NT $\geq$ 7.7 for both Nd and mK23.

**End point type**

Primary

**End point timeframe:**

Blood draws for the investigation of the humoral immune response were performed prior to the first vaccination (Encepur); after Dose 2; prior and after Dose 3; and for the 1-year, 2-year and 3-year post-Dose 3.

**Notes:**

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This was a descriptive study not powered to show superiority/ non-inferiority of any product. No formal hypothesis testing or statistical comparisons were pre-specified or conducted for the primary endpoint.

[5] - 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: This was a descriptive study not powered to show superiority/ non-inferiority of any product. FSME-IMMUN group results are reported as separate primary endpoint.

| <b>End point values</b>                | ENCEPUR group      |  |  |  |
|----------------------------------------|--------------------|--|--|--|
| Subject group type                     | Reporting group    |  |  |  |
| Number of subjects analysed            | 218 <sup>[6]</sup> |  |  |  |
| Units: %                               |                    |  |  |  |
| 6-Day Postdose 2 Per-Protocol (N=87)   | 93                 |  |  |  |
| 1-Month Postdose 2 Per-Protocol (N=87) | 92                 |  |  |  |
| Predose 3 Per-Protocol (N=172)         | 73                 |  |  |  |
| 6-Day Postdose 3 Per-Protocol (N=76)   | 91                 |  |  |  |
| 1-Month Postdose 3 Per-Protocol (N=85) | 99                 |  |  |  |
| 1-Year Postdose 3 Per-Protocol (N=155) | 95                 |  |  |  |
| 2-Year Postdose 3 Per-Protocol (N=144) | 96                 |  |  |  |
| 3-Year Postdose 3 Per-Protocol (N=131) | 90                 |  |  |  |

**Notes:**

[6] - Total number of subjects vaccinated with Encepur.

**Statistical analyses**

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

Information on SAEs were only to be collected from first vaccination through 28 calendar days after administration of the second vaccination and from the administration of the third vaccination through 28 calendar days thereafter.

Adverse event reporting additional description:

SAEs that occurred during the active collection period and any time after the active collection period were reportable if the Investigator suspected a causal relationship between the study vaccination and the SAE.

There was 1 SAE collected in the study that was unrelated to study vaccine; a participant was hospitalized for a hemorrhoidectomy.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 26.0   |

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | FSME-IMMUN Group |
|-----------------------|------------------|

Reporting group description:

No vaccine-related SAEs were reported in the study.

|                       |               |
|-----------------------|---------------|
| Reporting group title | ENCEPUR Group |
|-----------------------|---------------|

Reporting group description:

No vaccine-related SAEs were reported in the study.

There was 1 SAE collected in the study that was unrelated to study vaccine (Encepur). A participant was hospitalized for a hemorrhoidectomy.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There are no non-serious adverse events recorded in this study.

| Serious adverse events                            | FSME-IMMUN Group                                                                                                                                           | ENCEPUR Group   |  |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--|
| Total subjects affected by serious adverse events |                                                                                                                                                            |                 |  |
| subjects affected / exposed                       | 0 / 218 (0.00%)                                                                                                                                            | 1 / 218 (0.46%) |  |
| number of deaths (all causes)                     | 0                                                                                                                                                          | 0               |  |
| number of deaths resulting from adverse events    |                                                                                                                                                            | 0               |  |
| Gastrointestinal disorders                        |                                                                                                                                                            |                 |  |
| Hemorrhoidectomy                                  | Additional description: There was 1 SAE collected in the study that was unrelated to study vaccine; a participant was hospitalized for a hemorrhoidectomy. |                 |  |
| subjects affected / exposed                       | 0 / 218 (0.00%)                                                                                                                                            | 1 / 218 (0.46%) |  |
| occurrences causally related to treatment / all   | 0 / 0                                                                                                                                                      | 0 / 1           |  |
| deaths causally related to treatment / all        | 0 / 0                                                                                                                                                      | 0 / 0           |  |

Frequency threshold for reporting non-serious adverse events: 0 %

| <b>Non-serious adverse events</b>                     | FSME-IMMUN Group | ENCEPUR Group   |  |
|-------------------------------------------------------|------------------|-----------------|--|
| Total subjects affected by non-serious adverse events |                  |                 |  |
| subjects affected / exposed                           | 0 / 218 (0.00%)  | 0 / 218 (0.00%) |  |

## 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

|                                                                                              |
|----------------------------------------------------------------------------------------------|
| This was a descriptive study not powered to show superiority/non-inferiority of any product. |
|----------------------------------------------------------------------------------------------|

Notes: