



## Clinical trial results:

**A randomised, double-blind study of the safety and efficacy of Neoven compared to Vaminolact® in infants and children requiring long-term parenteral nutrition**

### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2009-012604-92   |
| Trial protocol           | FR               |
| Global end of trial date | 01 February 2011 |

### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 09 March 2019 |
| First version publication date | 09 March 2019 |

### Trial information

#### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | 05-NEOV-004 |
|-----------------------|-------------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Fresenius Kabi Deutschland GmbH   |
| Sponsor organisation address | Borkenberg 14, Oberursel, Germany, 61440  |
| Public contact               | Divisional Medical & Clinical Affairs Clinical Nutrition & Ketosteril, Fresenius Kabi Deutschland GmbH, trial-disclosure@fresenius-kabi.com |
| Scientific contact           | Divisional Medical & Clinical Affairs Clinical Nutrition & Ketosteril, Fresenius Kabi Deutschland GmbH, trial-disclosure@fresenius-kabi.com |

Notes:

### Paediatric regulatory details

|  |                     |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-000042-PIP01-07 |
| 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:

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**Results analysis stage**

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 27 December 2011 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 01 February 2011 |
| Was the trial ended prematurely?                     | Yes              |

Notes:

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**General information about the trial**

Main objective of the trial:

The main objective of the trial was to evaluate the safety of Neoven compared to Vaminolact in infants and children requiring long-term parenteral nutrition (PN).

Protection of trial subjects:

Subject protection was ensured by high medical and ethical standards in accordance with Declaration of Helsinki, Good Clinical Practice and applicable national and local laws and regulations. The signed informed consent was obtained from the legal representative of the patient prior to inclusion in the study.

Background therapy: -

Evidence for comparator: -

|   |                   |
|---|-------------------|
| Actual start date of recruitment                          | 01 September 2010 |
| Long term follow-up planned                               | No                |
| Independent data monitoring committee (IDMC) involvement? | Yes               |

Notes:

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**Population of trial subjects****Subjects enrolled per country**

|                                      |           |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | France: 6 |
| Worldwide total number of subjects   | 6         |
| EEA total number of subjects         | 6         |

Notes:

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**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)  | 1 |
| Children (2-11 years)                     | 5 |
| Adolescents (12-17 years)                 | 0 |
| Adults (18-64 years)                      | 0 |
| From 65 to 84 years                       | 0 |
| 85 years and over                         | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Overall, 6 patients were enrolled in the study in 2 centers in France, thereof 3 patients in the Neoven group and 3 patients in the Vaminolact group.

### Pre-assignment

Screening details:

Screened were male and female infants, aged from 1 month up to 11 years, with intestinal malabsorption requiring PN.

### Period 1

|                              |   |
|------------------------------|---|
| Period 1 title               | Overall trial (overall period)                                |
| Is this the baseline period? | Yes   |
| Allocation method            | Randomised - controlled                                       |
| Blinding used                | Double blind  |
| Roles blinded                | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Blinding implementation details:

Study medication was provided as bulk products to the responsible laboratory for masking due to the different strengths of products: Neoven has strength of 10 % and Vaminolact of 6.5 %. Neoven was diluted to a strength of 6.5 %. The responsible pharmacist provided a blinded final PN product which did not reveal any treatment allocation. Additional independent unblinded study monitor checked adherence to pre-defined working procedures.

### Arms

|                              |        |
|------------------------------|--------|
| Are arms mutually exclusive? | Yes    |
| <b>Arm title</b>             | Neoven |

Arm description:

Participants received Neoven to provide AA in the frame of a complete parenteral nutrition.

|  |                       |
|--|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Neoven                |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Neoven was planned to be infused for 12 consecutive weeks over 4 days to 7 days per week for approximately 10 to 24 hours per day.

In children up to 2 years: 2.0 to 2.5 g AA/kg body weight (bw) per day

In children from 2 to 11 years: 1.5 to-2.0 g AA/kg bw per day.

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Vaminolact |
|------------------|------------|

Arm description:

Participants received Vaminolact to provide AA in the frame of a complete parenteral nutrition.

|  |                         |
|--|-------------------------|
| Arm type                               | Active comparator       |
| Investigational medicinal product name | Vaminolact              |
| Investigational medicinal product code |                         |
| Other name                             | Vaminolac, Vamin Infant |
| Pharmaceutical forms                   | Solution for infusion   |
| Routes of administration               | Intravenous use         |

Dosage and administration details:

Vaminolact was planned to be infused for 12 consecutive weeks over 4 days to 7 days per week for approximately 10 to 24 hours per day.

In children up to 2 years: 2.0 to 2.5 g AA/kg body weight (bw) per day

In children from 2 to 11 years: 1.5 to-2.0 g AA/kg bw per day.

| <b>Number of subjects in period 1</b> | Neoven | Vaminolact |
|---------------------------------------|--------|------------|
| Started                               | 3      | 3          |
| Completed                             | 3      | 3          |

## Baseline characteristics

### Reporting groups

|   |            |
|---|------------|
| Reporting group title   | Neoven     |
| Reporting group description:  |            |
| Participants received Neoven to provide AA in the frame of a complete parenteral nutrition.     |            |
| Reporting group title   | Vaminolact |
| Reporting group description:  |            |
| Participants received Vaminolact to provide AA in the frame of a complete parenteral nutrition. |            |

| Reporting group values                             | Neoven | Vaminolact | Total |
|--|--------|------------|-------|
| Number of subjects                                 | 3      | 3          | 6     |
| 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)           | 1      | 0          | 1     |
| Children (2-11 years)                              | 2      | 3          | 5     |
| Adolescents (12-17 years)                          | 0      | 0          | 0     |
| Adults (18-64 years)                               | 0      | 0          | 0     |
| From 65-84 years                                   | 0      | 0          | 0     |
| 85 years and over                                  | 0      | 0          | 0     |
| Gender categorical                                 |        |            |       |
| Units: Subjects                                    |        |            |       |
| Female   | 1      | 2          | 3     |
| Male   | 2      | 1          | 3     |

## End points

### End points reporting groups

|   |            |
|---|------------|
| Reporting group title   | Neoven     |
| Reporting group description:  |            |
| Participants received Neoven to provide AA in the frame of a complete parenteral nutrition.     |            |
| Reporting group title   | Vaminolact |
| Reporting group description:  |            |
| Participants received Vaminolact to provide AA in the frame of a complete parenteral nutrition. |            |

### Primary: Occurrence of hyperammonaemia

|   |  |
|---|--|
| End point title   | Occurrence of hyperammonaemia <sup>[1]</sup> |
| End point description:  |  |
| The primary variables were evaluated as safety parameters. The assessment of hyperammonaemia was based on the ammonia measurements.   |  |
| End point type  | Primary                                      |
| End point timeframe:  |  |
| In Week 4, Week 8 and Week 12 ( $\pm$ 3 days) or if patient dropped out prematurely, after completion of last study treatment. At the same time of day, preferably 2 to 12 hours after completion of weekly infusion and before start of next infusion. |  |

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: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Occurrence of metabolic acidosis

|  |   |
|--|---|
| End point title  | Occurrence of metabolic acidosis <sup>[2]</sup> |
| End point description:   |   |
| The primary variables were evaluated as safety parameters. Metabolic acidosis was assessed from pH                             |   |
| End point type   | Primary   |
| End point timeframe:   |   |
| In Week 4, Week 8 and Week 12 ( $\pm$ 3 days) or if patient dropped out prematurely, after completion of last study treatment. |   |

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: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Occurrence of azotaemia

|                 |  |
|-----------------|--|
| End point title | Occurrence of azotaemia <sup>[3]</sup> |
|-----------------|--|

End point description:

The primary variables were evaluated as safety parameters. Azotaemia was assessed from blood urea nitrogen.

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

End point timeframe:

In Week 4, Week 8 and Week 12 ( $\pm$  3 days) or if patient dropped out prematurely, after completion of last study treatment. At the same time of day, preferably 2 to 12 hours after completion of weekly infusion and before start of next infusion.

Notes:

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

Justification: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Occurrence of hyperaminoacidaemia

|                 |  |
|-----------------|--|
| End point title | Occurrence of hyperaminoacidaemia <sup>[4]</sup> |
|-----------------|--|

End point description:

The primary variables were evaluated as safety parameters. Hyperaminoacidaemia was assessed based on measurements of AA.

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

End point timeframe:

In Week 4, Week 8 and Week 12 ( $\pm$  3 days) or if patient dropped out prematurely, after completion of last study treatment. At the same time of day, preferably 2 to 12 hours after completion of weekly infusion and before start of next infusion.

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: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Occurrence of hyperglycaemia

|   |   |
|---|---|
| End point title   | Occurrence of hyperglycaemia <sup>[5]</sup> |
| End point description:<br>The primary variables were evaluated as safety parameters. Hyperglycaemia was assessed based on measurements of blood glucose.  |   |
| End point type  | Primary                                     |
| End point timeframe:<br>In Week 4, Week 8 and Week 12 ( $\pm$ 3 days) or if patient dropped out prematurely, after completion of last study treatment. At the same time of day, preferably 2 to 12 hours after completion of weekly infusion and before start of next infusion. |   |

Notes:

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

Justification: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Occurrence of hepatic function/dysfunction

|   |   |
|---|---|
| End point title   | Occurrence of hepatic function/dysfunction <sup>[6]</sup> |
| End point description:<br>The primary variables were evaluated as safety parameters.<br>Hepatic function parameters were the following: ammonia levels, aspartate aminotransferase [AST], alanine aminotransferase [ALT], alkaline Phosphatase [AP], gamma-glutamyltranspeptidase [GGT], direct bilirubin and total bilirubin levels. |   |



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

End point timeframe:

In Week 4, Week 8 and Week 12 ( $\pm$  3 days) or if patient dropped out prematurely, after completion of last study treatment. At the same time of day, preferably 2 to 12 hours after completion of weekly infusion and before start of next infusion.

Notes:

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

Justification: Due to the premature termination of the study, it was decided to produce an abridged statistical evaluation only. All planned inference statistics were dropped.

| End point values                                | Neoven          | Vaminolact      |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                              | Reporting group | Reporting group |  |  |
| Number of subjects analysed                     | 3               | 3               |  |  |
| Units: Number of Subjects with at Least 1 Event | 0               | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From receipt of informed consent until the end of follow-up (7 days for AEs and 4 weeks for serious AEs after last treatment).

Adverse event reporting additional description:

All SAEs and all treatment-emergent AEs, occurred in the studies, are listed below.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 13.0   |

### Reporting groups

|                       |        |
|-----------------------|--------|
| Reporting group title | Neoven |
|-----------------------|--------|

Reporting group description:

Participants received Neoven to provide AA in the frame of a complete parenteral nutrition.

|                       |            |
|-----------------------|------------|
| Reporting group title | Vaminolact |
|-----------------------|------------|

Reporting group description:

Participants received Vaminolact to provide AA in the frame of a complete parenteral nutrition.

| Serious adverse events                               | Neoven         | Vaminolact     |  |
|--|----------------|----------------|--|
| Total subjects affected by serious adverse events    |                |                |  |
| subjects affected / exposed                          | 1 / 3 (33.33%) | 2 / 3 (66.67%) |  |
| number of deaths (all causes)                        | 0              | 0              |  |
| number of deaths resulting from adverse events       | 0              | 0              |  |
| General disorders and administration site conditions |                |                |  |
| Device breakage                                      |                |                |  |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 1 / 3 (33.33%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Infections and infestations                          |                |                |  |
| Ear infection  |                |                |  |
| subjects affected / exposed                          | 1 / 3 (33.33%) | 0 / 3 (0.00%)  |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Subcutaneous abscess                                 |                |                |  |
| subjects affected / exposed                          | 1 / 3 (33.33%) | 0 / 3 (0.00%)  |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |

|   |               |                |  |
|---|---------------|----------------|--|
| Staphylococcal sepsis                           |               |                |  |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 3 (33.33%) |  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          |  |
| Pharyngitis                                     |               |                |  |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 3 (33.33%) |  |
| 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>                     | Neoven          | Vaminolact      |  |
|---|-----------------|-----------------|--|
| Total subjects affected by non-serious adverse events |                 |                 |  |
| subjects affected / exposed                           | 3 / 3 (100.00%) | 3 / 3 (100.00%) |  |
| Investigations  |                 |                 |  |
| Prealbumin decreased                                  |                 |                 |  |
| subjects affected / exposed                           | 1 / 3 (33.33%)  | 2 / 3 (66.67%)  |  |
| occurrences (all)                                     | 1               | 2               |  |
| Haematocrit decreased                                 |                 |                 |  |
| subjects affected / exposed                           | 1 / 3 (33.33%)  | 1 / 3 (33.33%)  |  |
| occurrences (all)                                     | 1               | 1               |  |
| Blood sodium decreased                                |                 |                 |  |
| subjects affected / exposed                           | 0 / 3 (0.00%)   | 1 / 3 (33.33%)  |  |
| occurrences (all)                                     | 0               | 1               |  |
| Platelet count decreased                              |                 |                 |  |
| subjects affected / exposed                           | 0 / 3 (0.00%)   | 1 / 3 (33.33%)  |  |
| occurrences (all)                                     | 0               | 2               |  |
| Red blood cell count decreased                        |                 |                 |  |
| subjects affected / exposed                           | 0 / 3 (0.00%)   | 1 / 3 (33.33%)  |  |
| occurrences (all)                                     | 0               | 1               |  |
| Heart rate increased                                  |                 |                 |  |
| subjects affected / exposed                           | 0 / 3 (0.00%)   | 1 / 3 (33.33%)  |  |
| occurrences (all)                                     | 0               | 1               |  |
| White blood cell count decreased                      |                 |                 |  |

|   |  |  |  |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Blood pressure systolic increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>PCO2 increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Blood albumin decreased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>1 / 3 (33.33%)</p> <p>1</p> <p>1 / 3 (33.33%)</p> <p>1</p> <p>1 / 3 (33.33%)</p> <p>1</p> | <p>1 / 3 (33.33%)</p> <p>1</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |  |
| <p>General disorders and administration site conditions</p> <p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Device leakage</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 3 (33.33%)</p> <p>1</p> <p>0 / 3 (0.00%)</p> <p>0</p>   | <p>1 / 3 (33.33%)</p> <p>1</p> <p>1 / 3 (33.33%)</p> <p>1</p>  |  |
| <p>Eye disorders</p> <p>Conjunctivitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>0 / 3 (0.00%)</p> <p>0</p>  | <p>1 / 3 (33.33%)</p> <p>1</p>   |  |
| <p>Gastrointestinal disorders</p> <p>Toothache</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyperchlorhydria</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 3 (33.33%)</p> <p>1</p> <p>1 / 3 (33.33%)</p> <p>1</p>  | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>  |  |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Pharyngeal inflammation</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 3 (33.33%)</p> <p>1</p> <p>1 / 3 (33.33%)</p> <p>1</p>  | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>  |  |

|  |                |                |  |
|--|----------------|----------------|--|
| Skin and subcutaneous tissue disorders |                |                |  |
| Dermatitis diaper                      |                |                |  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 0 / 3 (0.00%)  |  |
| occurrences (all)                      | 1              | 0              |  |
| Infections and infestations            |                |                |  |
| Rhinitis                               |                |                |  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 1 / 3 (33.33%) |  |
| occurrences (all)                      | 1              | 1              |  |
| Nasopharyngitis                        |                |                |  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 1 / 3 (33.33%) |  |
| occurrences (all)                      | 1              | 1              |  |
| Ear infection                          |                |                |  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 3 (33.33%) |  |
| occurrences (all)                      | 0              | 3              |  |

## 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.

Premature termination of the study.

Only abridged evaluation was performed without any summary tables or inferential statistical testing.

Only patient data listings based on all randomized patients were computed.

Notes: