



Clinical trial results:

A Randomized, Open-Label, Active-Controlled Study of the Safety, Efficacy, and Pharmacokinetics of Ferumoxytol Compared with Oral Iron for the Treatment of Iron Deficiency Anemia in Pediatric Subjects with Nondialysis-dependent Chronic Kidney Disease

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2010-019388-12 |
| Trial protocol | DE GB HU RO LT ES BG |
| Global end of trial date | 24 June 2014 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 13 December 2017 |
| First version publication date | 13 December 2017 |

Trial information

Trial identification

| | |
|-----------------------|------------------|
| Sponsor protocol code | AMAG-FER-CKD-252 |
|-----------------------|------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01155388 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AMAG Pharmaceuticals, Inc. |
| Sponsor organisation address | 1100 Winter Street, Waltham , United States, 02451 |
| Public contact | Medical Information, AMAG Pharmaceuticals, Inc., +1 877-411-2510, amag@druginfo.com |
| Scientific contact | Medical Information, AMAG Pharmaceuticals, Inc., +1 877-411-2510, amag@druginfo.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000373-PIP02-09 |
| 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? | Yes |

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 24 June 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 24 June 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 June 2014 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

This study (AMAG-FER-CKD-252) was a study evaluating the efficacy and safety of intravenous (IV) ferumoxytol in pediatric participants with nondialysis-dependent chronic kidney disease (CKD). Study AMAG-FER-CKD-251 (2010-019387-37) was a study evaluating the efficacy and safety of IV ferumoxytol in pediatric participants with dialysis-dependent CKD.

Due to significant challenges with enrollment for both studies, Study AMAG-FER-CKD-252 was combined with Study AMAG-FER-CKD-251 and enrollment continued under Study AMAG-FER-CKD-251. The significant challenges with enrollment then led the sponsor to discontinue the combined AMAG FER-CKD-251 and AMAG FERCKD-252 studies. The analysis of the primary completion data and the results for the combined studies are included in this record. The enrollment number (n=14) includes the number of participants for both AMAG-FER-CKD-251 and AMAG-FER-CKD-252 studies, combined.

Protection of trial subjects:

These studies were conducted according to international standards of Good Clinical Practice, International Conference on Harmonization (ICH), United States Food and Drug Administration regulations, applicable government regulations, and institutional research policies and procedures. AMAG will also continue to support the principles of the Declaration of Helsinki.

All participants were to remain in the clinic for 1 hour following each IV injection of ferumoxytol, with frequent monitoring of vital signs and close observation for adverse events.

Background therapy:

There was no background therapy administered across all participant groups.

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 17 October 2011 |
| 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 | Poland: 1 |
| Country: Number of subjects enrolled | Spain: 1 |
| Country: Number of subjects enrolled | Germany: 1 |
| Country: Number of subjects enrolled | Mexico: 2 |
| Country: Number of subjects enrolled | Peru: 4 |
| Country: Number of subjects enrolled | United States: 5 |
| Worldwide total number of subjects | 14 |
| EEA total number of subjects | 3 |

Notes:

| Subjects enrolled per age group | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 1 |
| Adolescents (12-17 years) | 13 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study population consisted of pediatric participants (6 months to <18 years of age) with iron deficiency anemia defined as hemoglobin <12.0 grams/deciliter and with either transferrin saturation ≤40% or ferritin <100 nanograms/milliliter (mL) and CKD.

Pre-assignment

Screening details:

Screening was to take place within 2 weeks of the start of the study. Screening assessments included review of inclusion/exclusion criteria, signature of informed consent, medical history, vital signs measurement, physical examination, clinical laboratory assessments including iron panel, and start of adverse event capture.

Period 1

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

Blinding implementation details:

This was a randomized, open-label (not blinded) study. Participants were to be randomized to either IV ferumoxytol or oral iron supplementation.

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Ferumoxytol |

Arm description:

Participants received 1 of the following 2 ferumoxytol dose regimens:

- Four IV injections of ferumoxytol 3.5 milligrams (mg) oral iron (Fe)/kilogram (kg) (maximum of 255 mg/dose) administered on nonconsecutive days within a 14-day period as follows: Day 1 (dose 1), Days 3* through 10 (dose 2), Days 5 through 12 (dose 3), and Days 7 through 14 (dose 4). *Participants participating in pharmacokinetic (PK) sampling received the second dose on Day 4 after the 72-hour PK sample was collected.

- Two IV injections of ferumoxytol 7.0 mg Fe/kg (maximum of 510 mg/dose), the first administered on Day 1 and the second on Days 3 through 9.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Ferumoxytol |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Ferumoxytol for IV injection: Each 20 mL single-use vial contains 17 mL of ferumoxytol that consists of iron, at a concentration of 30 mg Fe/mL, and mannitol, at a concentration of 44 mg/mL, in a black to reddish brown sterile, aqueous, colloidal, isotonic solution. The product contains no preservatives. Osmolality: 270-330 milliosmoles/kg; pH: 6-8.

Administration was either: 4 IV injections of ferumoxytol 3.5 mg Fe/kg (maximum 255 mg/dose) administered on nonconsecutive days within a 14-day period as follows: Day 1 (dose 1), Days 3* through 10 (dose 2), Days 5 through 12 (dose 3), and Days 7 through 14 (dose 4); or 2 IV injections of ferumoxytol 7.0 mg Fe/kg (maximum 510 mg/dose), the first administered on Day 1 and the second on Days 3* through 9.

*Participants participating in PK sampling were to receive the second dose on Day 4 after the 72-hour PK sample was collected.

| | |
|------------------|-----------|
| Arm title | Oral Iron |
|------------------|-----------|

Arm description:

Participants received oral iron (2.5 mg Fe/kg) twice daily (maximum 100 mg/dose) on Days 1 through 35.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Ferrous Fumarate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral liquid |
| Routes of administration | Oral use |

Dosage and administration details:

Liquid oral iron preparation (ferrous fumarate) 2.5 mg Fe/kg, administered twice daily (maximum of 100 mg/dose) on Days 1 through 35.

| Number of subjects in period 1 | Ferumoxytol | Oral Iron |
|--|-------------|-----------|
| Started | 8 | 6 |
| Received at Least One Dose of Study Drug | 8 | 6 |
| Completed | 7 | 6 |
| Not completed | 1 | 0 |
| Adverse event, non-fatal | 1 | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Ferumoxytol |
|-----------------------|-------------|

Reporting group description:

Participants received 1 of the following 2 ferumoxytol dose regimens:

- Four IV injections of ferumoxytol 3.5 milligrams (mg) oral iron (Fe)/kilogram (kg) (maximum of 255 mg/dose) administered on nonconsecutive days within a 14-day period as follows: Day 1 (dose 1), Days 3* through 10 (dose 2), Days 5 through 12 (dose 3), and Days 7 through 14 (dose 4). *Participants participating in pharmacokinetic (PK) sampling received the second dose on Day 4 after the 72-hour PK sample was collected.

- Two IV injections of ferumoxytol 7.0 mg Fe/kg (maximum of 510 mg/dose), the first administered on Day 1 and the second on Days 3 through 9.

| | |
|-----------------------|-----------|
| Reporting group title | Oral Iron |
|-----------------------|-----------|

Reporting group description:

Participants received oral iron (2.5 mg Fe/kg) twice daily (maximum 100 mg/dose) on Days 1 through 35.

| Reporting group values | Ferumoxytol | Oral Iron | Total |
|---|-------------|-----------|-------|
| Number of subjects | 8 | 6 | 14 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 1 | 1 |
| Adolescents (12-17 years) | 8 | 5 | 13 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 15.2 | 13.8 | |
| standard deviation | ± 1.65 | ± 4.52 | - |
| Gender categorical Units: Subjects | | | |
| Female | 5 | 1 | 6 |
| Male | 3 | 5 | 8 |

End points

End points reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Ferumoxytol |
|-----------------------|-------------|

Reporting group description:

Participants received 1 of the following 2 ferumoxytol dose regimens:

- Four IV injections of ferumoxytol 3.5 milligrams (mg) oral iron (Fe)/kilogram (kg) (maximum of 255 mg/dose) administered on nonconsecutive days within a 14-day period as follows: Day 1 (dose 1), Days 3* through 10 (dose 2), Days 5 through 12 (dose 3), and Days 7 through 14 (dose 4). *Participants participating in pharmacokinetic (PK) sampling received the second dose on Day 4 after the 72-hour PK sample was collected.

- Two IV injections of ferumoxytol 7.0 mg Fe/kg (maximum of 510 mg/dose), the first administered on Day 1 and the second on Days 3 through 9.

| | |
|-----------------------|-----------|
| Reporting group title | Oral Iron |
|-----------------------|-----------|

Reporting group description:

Participants received oral iron (2.5 mg Fe/kg) twice daily (maximum 100 mg/dose) on Days 1 through 35.

| | |
|----------------------------|-------------------|
| Subject analysis set title | Safety Population |
|----------------------------|-------------------|

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

Subject analysis set description:

The Safety Population includes all randomized participants who had any exposure to study drug (ferumoxytol or oral iron); the safety analysis is based on actual treatment received. Data are for the combined AMAG-FER-CKD-251 and AMAG-FER-CKD-252 studies.

| | |
|----------------------------|----------------------------------|
| Subject analysis set title | Intent-to-Treat (ITT) Population |
|----------------------------|----------------------------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Intention-to-treat |
|---------------------------|--------------------|

Subject analysis set description:

The ITT Population included all randomized participants who had received at least 1 dose of study drug. Sample data were collected, but not run through any analysis to obtain end point data. As such, summary of the data set is not possible.

| | |
|----------------------------|---------------|
| Subject analysis set title | PK Population |
|----------------------------|---------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

The PK Population included all randomized participants who received at least 1 dose of study drug and consented to PK sampling. Of the 14 participants who participated in the studies, only 1 participated in the PK sampling of the study. Sample data were collected, but not run through any analysis to obtain end point data. As such, summary of the data set is not possible.

Primary: Mean Change In Hemoglobin From Baseline To Week 5

| | |
|-----------------|--|
| End point title | Mean Change In Hemoglobin From Baseline To Week 5 ^[1] |
|-----------------|--|

End point description:

Mean changes in hemoglobin from Baseline to Week 5 were to be presented. Despite efforts to complete the studies as designed, several factors contributed to significant challenges in enrollment and led the Sponsor to discontinue the combined AMAG FER-CKD-251 and AMAG FER-CKD-252 studies. Blood samples were collected, but not run through an analysis to obtain end point data. As such, the data set for this primary end point cannot be summarized nor can the statistical analysis, as described in the protocol, be provided in a way that will provide any significant data based upon the limited study datasets.

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

End point timeframe:

Baseline, Week 5

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: Sample data were collected, but not run through any analysis to obtain end point data. As such, summary and statistical analysis of the data set is not possible.

| End point values | Ferumoxytol | Oral Iron | | |
|-----------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | | |
| Units: participants | | | | |

Notes:

[2] - Sample data were collected, but not run through any analysis to obtain end point data.

[3] - Sample data were collected, but not run through any analysis to obtain end point data.

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics: Area Under The Curve Of Ferumoxytol

| | |
|-----------------|---|
| End point title | Pharmacokinetics: Area Under The Curve Of Ferumoxytol |
|-----------------|---|

End point description:

Ferumoxytol concentrations were to be determined using a drug-specific nuclear magnetic resonance assay. Blood samples were to be collected at specified times predose and postdose at the time of the first dose from 6 participants in each age-dose group. Sampling for participants <6 years of age will be minimized to the fewest number of time points required for population PK analysis based on preliminary PK data from the first 2 age cohorts. Blood samples were collected, but not run through an analysis to obtain end point data. As such, the data set for this secondary end point cannot be summarized in a way that will provide any significant data based upon the limited study datasets.

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

End point timeframe:

Baseline, 10, 30, 120, and 360 minutes postdose, and 24, 48, and 72 hours postdose

| End point values | Ferumoxytol | Oral Iron | | |
|-----------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[4] | 0 ^[5] | | |
| Units: participants | | | | |

Notes:

[4] - No analyses were performed as there was only 1 participant in the PK portion.

[5] - No analyses were performed as there was only 1 participant in the PK portion.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Randomization up to 7 weeks (Follow-up).

Adverse event reporting additional description:

Due to significant challenges with enrollment for both studies, Study AMAG-FER-CKD-252 was combined with Study AMAG-FER-CKD-251 and enrollment continued under Study AMAG-FER-CKD-251. The adverse events for the combined studies are included in this record.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 13.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Ferumoxytol |
|-----------------------|-------------|

Reporting group description:

Participants received 1 of the following 2 ferumoxytol dose regimens:

- Four IV injections of ferumoxytol 3.5 milligrams (mg) oral iron (Fe)/kilogram (kg) (maximum of 255 mg/dose) administered on nonconsecutive days within a 14-day period as follows: Day 1 (dose 1), Days 3* through 10 (dose 2), Days 5 through 12 (dose 3), and Days 7 through 14 (dose 4). *Participants participating in PK sampling received the second dose on Day 4 after the 72-hour PK sample was collected.

- Two IV injections of ferumoxytol 7.0 mg Fe/kg (maximum of 510 mg/dose), the first administered on Day 1 and the second between Days 3 through 9.

| | |
|-----------------------|-----------|
| Reporting group title | Oral Iron |
|-----------------------|-----------|

Reporting group description:

Participants received oral iron (2.5 mg Fe/kg) twice daily (maximum 100 mg/dose) on Days 1 through 35.

| Serious adverse events | Ferumoxytol | Oral Iron | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 6 (16.67%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Infections and infestations | | | |
| Acute gastroenteritis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 6 (16.67%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperkalaemia | | | |

| | | | |
|---|----------------|---------------|--|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 6 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Ferumoxytol | Oral Iron | |
|---|----------------|----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 8 (75.00%) | 5 / 6 (83.33%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Psychiatric disorders | | | |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Investigations | | | |

| | | | |
|---|---------------------|---------------------|--|
| Residual urine volume decreased subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Injury, poisoning and procedural complications | | | |
| Procedural hypotension subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Procedural nausea subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Skin injury subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Cardiac disorders | | | |
| Ventricular flutter subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Blood and lymphatic system disorders | | | |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Gastrointestinal disorders | | | |
| Food poisoning subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal pain subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Infections and infestations | | | |
| Chronic sinusitis subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Pneumonia | | | |

| | | | |
|---|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Viral pharyngitis subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Pharyngitis subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 6 (0.00%) 0 | |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Metabolism and nutrition disorders | | | |
| Hypermagnesaemia subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Fluid retention subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 1 / 6 (16.67%) 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|--|
| 09 May 2013 | <p>Major changes included: combined dialysis and nondialysis-dependent participants (nondialysis-dependent participants previously studied separately in CKD-252 were combined with CKD-251); updated total number of participants from 144 to 288; inclusion/exclusion criteria changes; administrative changes.</p> <p>Rationale for changes included: conducting a single protocol in CKD participants aligned with the current approved label (potential efficiencies gained in the conduct of a single protocol); modification of entry criteria based on feedback from physicians regarding iron treatment protocols in this population.</p> |
| 12 July 2013 | <p>Major change was the change in comparator sourcing.</p> <p>The rationale for the change was that the original comparator supply (ferrous sulfate) expired on 30-Jun-2013 and was no longer being manufactured. As such, the Sponsor identified a new comparator product (ferrous fumarate) to be used in the clinical study.</p> |

Notes:

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.

While sample data were collected, it was not run through any analysis to obtain the necessary end point data. As such, summary of the data set is not possible.

Notes: