



Clinical trial results:

A Two-stage 6-month, Multicentre, Randomised, Double-blind, Controlled Study on the Safety and Efficacy of a Single Intra-articular Administration of JTA-004 in Patients with Symptomatic Knee Osteoarthritis

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-002117-30 |
| Trial protocol | BE |
| Global end of trial date | 27 April 2018 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v2 (current) |
| This version publication date | 27 November 2019 |
| First version publication date | 01 November 2019 |
| Version creation reason | • Changes to summary attachments error in the upload of the summary |
| Summary attachment (see zip file) | summary report (BT_JTA-KOA1_CSR summary_EudraCT.pdf) |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | 000010/BT |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bone Therapeutics S.A. |
| Sponsor organisation address | rue Auguste Picard 37, Gosselies, Belgium, B-6041 |
| Public contact | Clinical Trial Information, Bone Therapeutics S.A., jta.koa1@bonetherapeutics.com |
| Scientific contact | Clinical Trial Information, Bone Therapeutics S.A., jta.koa1@bonetherapeutics.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 07 June 2019 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 April 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 April 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to assess the safety and efficacy of JTA-004® single intra-articular administration in patients suffering from symptomatic osteoarthritis of the knee at the end of the study period (at Month 6).

Safety:

At each follow-up visit, patients will be assessed for the occurrence of any (serious) adverse events using patient open non-directive questionnaire, physical examination (including vital signs), and laboratory measurements. The safety analyses will be based on incidence evaluation of treatment emergent adverse events by preferred term and body system. Laboratory measurements will be compared to the normal laboratory ranges and to laboratory measurements obtained at Baseline Visit.

Efficacy:

Primary study objectives are (i) the selection of the best JTA-004® strength and (ii) the superiority assessment of the best JTA-004® strength efficacy to the reference or (iii) stop the trial at interim analysis for futility.

Protection of trial subjects:

Declaration of Helsinki

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 01 February 2016 |
| 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 | Belgium: 164 |
| Worldwide total number of subjects | 164 |
| EEA total number of subjects | 164 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |

| | |
|--|-----|
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 55 |
| From 65 to 84 years | 109 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Men and women, aged 50 to 79 years old, diagnosed with primary knee OA having a previous insufficient/failed response to analgesics and/or nonsteroidal antiinflammatory drugs (NSAIDs).

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Screening |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Blinding implementation details:

The Investigators were blind to treatment assignments with respect to the patient evaluation. They recruited, included and assessed patients during the whole study followup period, but did not treat the patients. Investigators were therefore not aware of treatment assignment.

Patients were blind to treatment assignment

Arms

| | |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | JTA-004 50 2 mL |

Arm description:

Sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg; 2 mL injected

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | JTA-004 50 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
| Routes of administration | Intraarticular use |

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|-----------------|
| Arm title | JTA-004 50 4 mL |
|------------------|-----------------|

Arm description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg/ml. 4 mL injected

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | JTA-004 50 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
| Routes of administration | Intraarticular use |

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|------------------|
| Arm title | JTA-004 100 2 mL |
|------------------|------------------|

Arm description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 100 µg/ml. 2 mL injected

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | JTA-004 100 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
| Routes of administration | Intraarticular use |

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|-------------|
| Arm title | Synvisc One |
|------------------|-------------|

Arm description:

Synvisc-One

| | |
|--|--|
| Arm type | Active comparator |
| Investigational medicinal product name | Synvisc-One |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Intraarticular use |

Dosage and administration details:

Single injection

| Number of subjects in period 1 | JTA-004 50 2 mL | JTA-004 50 4 mL | JTA-004 100 2 mL |
|---------------------------------------|-----------------|-----------------|------------------|
| Started | 41 | 41 | 41 |
| Completed | 41 | 41 | 41 |

| Number of subjects in period 1 | Synvisc One |
|---------------------------------------|-------------|
| Started | 41 |
| Completed | 41 |

Period 2

| | |
|------------------------------|---------------------------------|
| Period 2 title | Final analysis |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Blinding implementation details:

The Investigators were blind to treatment assignments with respect to the patient evaluation. They recruited, included and assessed patients during the whole study followup period, but did not treat the patients. Investigators were therefore not aware of treatment assignment.

Patients were blind to treatment assignment

same intra-articular injection (performed by the Independent Physicians). As the appearance of the resuspended JTA-004 was differ

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|-----------------|
| Arm title | JTA-004 50 2 mL |
|------------------|-----------------|

Arm description:

Sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg; 2 mL injected

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|------------|
| Investigational medicinal product name | JTA-004 50 |
|--|------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|--|
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
|----------------------|--|

| | |
|--------------------------|--------------------|
| Routes of administration | Intraarticular use |
|--------------------------|--------------------|

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|-----------------|
| Arm title | JTA-004 50 4 mL |
|------------------|-----------------|

Arm description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg/ml. 4 mL injected

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|------------|
| Investigational medicinal product name | JTA-004 50 |
|--|------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|--|
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
|----------------------|--|

| | |
|--------------------------|--------------------|
| Routes of administration | Intraarticular use |
|--------------------------|--------------------|

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|------------------|
| Arm title | JTA-004 100 2 mL |
|------------------|------------------|

Arm description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 100 µg/ml. 2 mL injected

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|-------------|
| Investigational medicinal product name | JTA-004 100 |
|--|-------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|--|
| Pharmaceutical forms | Powder and solvent for solution for injection/infusion |
|----------------------|--|

| | |
|--------------------------|--------------------|
| Routes of administration | Intraarticular use |
|--------------------------|--------------------|

Dosage and administration details:

Single intra-articular injection

| | |
|------------------|-------------|
| Arm title | Synvisc One |
|------------------|-------------|

Arm description:

Synvisc-One

| | |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

| | |
|--|-------------|
| Investigational medicinal product name | Synvisc-One |
|--|-------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|--|
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
|----------------------|--|

| | |
|--------------------------|--------------------|
| Routes of administration | Intraarticular use |
|--------------------------|--------------------|

Dosage and administration details:

Single injection

| Number of subjects in period 2 | JTA-004 50 2 mL | JTA-004 50 4 mL | JTA-004 100 2 mL |
|---------------------------------------|-----------------|-----------------|------------------|
| Started | 41 | 41 | 41 |
| Completed | 41 | 41 | 41 |

| Number of subjects in period 2 | Synvisc One |
|---------------------------------------|-------------|
| Started | 41 |
| Completed | 41 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------|
| Reporting group title | Screening |
|-----------------------|-----------|

| |
|------------------------------|
| Reporting group description: |
|------------------------------|

| |
|--------|
| Adults |
|--------|

| Reporting group values | Screening | Total | |
|------------------------|-----------|-------|--|
| Number of subjects | 164 | 164 | |
| Age categorical | | | |
| Adults | | | |
| Units: Subjects | | | |
| Adults | 164 | 164 | |
| Age continuous | | | |
| Age | | | |
| Units: years | | | |
| arithmetic mean | 62.7 | | |
| standard deviation | ± 7.5 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 112 | 112 | |
| Male | 52 | 52 | |

End points

End points reporting groups

| | |
|--|------------------|
| Reporting group title | JTA-004 50 2 mL |
| Reporting group description: Sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg; 2 mL injected | |
| Reporting group title | JTA-004 50 4 mL |
| Reporting group description: sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg/ml. 4 mL injected | |
| Reporting group title | JTA-004 100 2 mL |
| Reporting group description: sodium hyaluronate content was 20 mg and the concentration of clonidine was 100 µg/ml. 2 mL injected | |
| Reporting group title | Synvisc One |
| Reporting group description: Synvisc-One | |
| Reporting group title | JTA-004 50 2 mL |
| Reporting group description: Sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg; 2 mL injected | |
| Reporting group title | JTA-004 50 4 mL |
| Reporting group description: sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg/ml. 4 mL injected | |
| Reporting group title | JTA-004 100 2 mL |
| Reporting group description: sodium hyaluronate content was 20 mg and the concentration of clonidine was 100 µg/ml. 2 mL injected | |
| Reporting group title | Synvisc One |
| Reporting group description: Synvisc-One | |

Primary: Womac pain subscale change from baseline

| | |
|--|--|
| End point title | Womac pain subscale change from baseline |
| End point description: The primary endpoint is the WOMAC® VA3.1 Pain Subscale (subscale A): the individual changes in WOMAC® VA3.1 Pain Subscale Score between Baseline and Month 6 were calculated and compared by analysis of covariance (ANCOVA), adjusted for baseline value, to the Reference group. | |
| End point type | Primary |
| End point timeframe: Evaluation at month 6 | |

| | | | | |
|--------------------------------------|------------------|-----------------|--|--|
| End point values | JTA-004 100 2 mL | Synvisc One | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 41 | 41 | | |
| Units: mm | | | | |
| arithmetic mean (standard deviation) | -26.7 (± 28.9) | -11.3 (± 27.9) | | |

Statistical analyses

| | |
|-----------------------------------|--------|
| Statistical analysis title | ANCOVA |
|-----------------------------------|--------|

Statistical analysis description:

The primary endpoint is the WOMAC® VA3.1 Pain Subscale (subscale A): the individual changes in WOMAC® VA3.1 Pain Subscale Score between Baseline and Month 6 were calculated and compared by analysis of covariance (ANCOVA), adjusted for baseline value, to the Reference group.

| | |
|---|--------------------------------|
| Comparison groups | JTA-004 100 2 mL v Synvisc One |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.05 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -9.49 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.21 |
| upper limit | 3.23 |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

6 months post injection

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

Dictionary used

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

| | |
|--------------------|-----|
| Dictionary version | 2.1 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|-----------------|
| Reporting group title | JTA-004 50 2 mL |
|-----------------------|-----------------|

Reporting group description:

Sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg; 2 mL injected

| | |
|-----------------------|-----------------|
| Reporting group title | JTA-004 50 4 mL |
|-----------------------|-----------------|

Reporting group description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 50 µg/mL. 4 mL injected

| | |
|-----------------------|------------------|
| Reporting group title | JTA-004 100 2 mL |
|-----------------------|------------------|

Reporting group description:

sodium hyaluronate content was 20 mg and the concentration of clonidine was 100 µg/mL. 2 mL injected

| | |
|-----------------------|-------------|
| Reporting group title | Synvisc One |
|-----------------------|-------------|

Reporting group description:

Synvisc-One

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: non-serious adverse event are discussed in the summary report

| Serious adverse events | JTA-004 50 2 mL | JTA-004 50 4 mL | JTA-004 100 2 mL |
|---|-----------------|-----------------|------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 41 (9.76%) | 1 / 41 (2.44%) | 1 / 41 (2.44%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 1 / 41 (2.44%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Gastrointestinal disorders | | | |
| Barett's oesophagus | | | |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diaorrhea | | | |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hernia eventration | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 1 / 41 (2.44%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Rectocele | | | |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 1 / 41 (2.44%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 1 / 41 (2.44%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 41 (0.00%) | 1 / 41 (2.44%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|--|--|
| Serious adverse events | Synvisc One | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 41 (4.88%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 1 / 41 (2.44%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Barett's oesophagus | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diaorrhea | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hernia eventration | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Rectocele | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 41 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | JTA-004 50 2 mL | JTA-004 50 4 mL | JTA-004 100 2 mL |
|---|-----------------|-----------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |

| Non-serious adverse events | Synvisc One | | |
|---|----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|-------------|
| 23 September 2016 | Amendment 1 |
| 10 May 2017 | Amendment 2 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported