



Clinical trial results:

Multicentre, randomized, double-blind, placebo-controlled clinical trial to evaluate the short-term efficacy and safety of two different treatment regimens of Betamethasone valerate 2.25 mg medicated plaster in patients with chronic tendinopathies of the upper and lower limbs

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-005030-11 |
| Trial protocol | IT |
| Global end of trial date | 24 April 2014 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 13 July 2019 |
| First version publication date | 13 July 2019 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | 12I-BMT08 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | IBSA Institut Biochimique SA |
| Sponsor organisation address | via del Piano 29, Pambio-Noranco, Switzerland, |
| Public contact | Stefano Rovati, IBSA Institut Biochimique SA, +41 583600000, stefano.rovati@ibsa.ch |
| Scientific contact | Stefano Rovati, IBSA Institut Biochimique SA, +41 583600000, stefano.rovati@ibsa.ch |

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 | 08 June 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 06 February 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 April 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to investigate the ability of betamethasone valerate 2.25 mg medicated plaster, as compared to placebo plaster (same formulation but without active ingredient), to reduce pain when topically applied daily, according to two different dose regimens (i.e., 12 or 24 hours of application/day), and during a period of 4 weeks, in patients suffering from chronic lateral elbow tendinopathy and chronic midportion Achilles tendinopathy.

Protection of trial subjects:

In case of insufficient pain relief, patients were allowed to take paracetamol 500 mg oral tablet as rescue medication, up to a maximum daily dose of 4 g.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 01 April 2013 |
| 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 | Italy: 102 |
| Worldwide total number of subjects | 102 |
| EEA total number of subjects | 102 |

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) | 95 |
| From 65 to 84 years | 7 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study Initiation Date: (First Patient First Visit) 24 Apr 2013
Study Completion Date: (Last Patient Last Visit) 06 Feb 2014

Pre-assignment

Screening details:

Patients suffering from ≥ 12 weeks of either from Chronic Lateral Elbow Tendinopathy or Chronic Midportion (or non-insertional) Achilles Tendinopathy in their symptomatic phase, defined as a pain ≥ 50 mm on a 0-100 mm VAS as perceived when performing a standardized movement

Period 1

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

Arms

| | |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | BMV plaster 24h |

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMV plaster 24h |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Medicated plaster |
| Routes of administration | Topical use |

Dosage and administration details:

One single plaster was topically applied once a day for 24 hours

| | |
|------------------|-----------------|
| Arm title | BMV plaster 12h |
|------------------|-----------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMV plaster 12h |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Medicated plaster |
| Routes of administration | Topical use |

Dosage and administration details:

One single plaster was topically applied once a day for 12 hours

| | |
|------------------|-------------|
| Arm title | PBO plaster |
|------------------|-------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Placebo |
| Investigational medicinal product name | PBO plaster |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Medicated plaster |
| Routes of administration | Topical use |

Dosage and administration details:

One single plaster was topically applied once a day for 12 or 24 hours

| Number of subjects in period 1 | BMV plaster 24h | BMV plaster 12h | PBO plaster |
|---------------------------------------|-----------------|-----------------|-------------|
| Started | 37 | 32 | 33 |
| Completed | 35 | 32 | 29 |
| Not completed | 2 | 0 | 4 |
| Consent withdrawn by subject | 1 | - | - |
| Adverse event, non-fatal | 1 | - | 2 |
| Lack of efficacy | - | - | 1 |
| Protocol deviation | - | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|-----------------|
| Reporting group title | BMV plaster 24h |
| Reporting group description: - | |
| Reporting group title | BMV plaster 12h |
| Reporting group description: - | |
| Reporting group title | PBO plaster |
| Reporting group description: - | |

| Reporting group values | BMV plaster 24h | BMV plaster 12h | PBO plaster |
|--|-----------------|-----------------|-------------|
| Number of subjects | 37 | 32 | 33 |
| 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 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 32 | 30 | 32 |
| From 65-84 years | 5 | 2 | 1 |
| 85 years and over | 0 | 0 | 0 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 17 | 12 | 19 |
| Male | 20 | 20 | 14 |

| Reporting group values | Total | | |
|--|-------|--|--|
| Number of subjects | 102 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 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) | 94 | | |
| From 65-84 years | 8 | | |
| 85 years and over | 0 | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 48 | | |
| Male | 54 | | |

End points

End points reporting groups

| | |
|--------------------------------|-----------------|
| Reporting group title | BMV plaster 24h |
| Reporting group description: - | |
| Reporting group title | BMV plaster 12h |
| Reporting group description: - | |
| Reporting group title | PBO plaster |
| Reporting group description: - | |

Primary: VAS Pain Reduction

| | |
|---|--------------------|
| End point title | VAS Pain Reduction |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| decrease of VAS Pain score (mm) from baseline to Day 28 | |

| End point values | BMV plaster 24h | BMV plaster 12h | PBO plaster | |
|--------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 37 | 32 | 33 | |
| Units: millimeter(s) | | | | |
| arithmetic mean (standard deviation) | 38.89 (± 29.80) | 37.47 (± 28.09) | 20.97 (± 23.27) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Primary Endpoint |
| Comparison groups | BMV plaster 24h v BMV plaster 12h v PBO plaster |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | ≤ 0.05 |
| Method | ANCOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events were evaluated at each visit.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------------|
| Reporting group title | BMV plaster 24h |
|-----------------------|-----------------|

Reporting group description: -

| | |
|-----------------------|-----------------|
| Reporting group title | BMV plaster 12h |
|-----------------------|-----------------|

Reporting group description: -

| | |
|-----------------------|-------------|
| Reporting group title | PBO plaster |
|-----------------------|-------------|

Reporting group description: -

| Serious adverse events | BMV plaster 24h | BMV plaster 12h | PBO plaster |
|---|-----------------|-----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 32 (0.00%) | 2 / 33 (6.06%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Nervous system disorders | | | |
| Transverse sinus thrombosis | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 32 (0.00%) | 1 / 33 (3.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 37 (0.00%) | 0 / 32 (0.00%) | 1 / 33 (3.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | BMV plaster 24h | BMV plaster 12h | PBO plaster |
|---|-----------------|-----------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 37 (24.32%) | 5 / 32 (15.63%) | 11 / 33 (33.33%) |

| | | | |
|--|-----------------|----------------|-----------------|
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 4 / 37 (10.81%) | 2 / 32 (6.25%) | 5 / 33 (15.15%) |
| occurrences (all) | 4 | 2 | 5 |
| General disorders and administration site conditions | | | |
| Application site erythema | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 32 (0.00%) | 1 / 33 (3.03%) |
| occurrences (all) | 1 | 0 | 1 |
| Application site oedema | | | |
| subjects affected / exposed | 1 / 37 (2.70%) | 0 / 32 (0.00%) | 0 / 33 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported