

A pivotal Phase IIb/III, multicentre, randomised, open, controlled study on the efficacy and safety of autologous osteoblastic cells (PREOB®) implantation in non-infected hypotrophic non-union fractures.

Published: 01-11-2012

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To determine the efficacy and the safety of PREOB, a proprietary population of autologous bone-forming cells, in the treatment of non-infected hypotrophic non-union fractures of long bones.

| | |
|------------------------------|----------------|
| Ethical review | Not approved |
| Status | Will not start |
| Health condition type | Fractures |
| Study type | Interventional |

Summary

ID

NL-OMON37100

Source

ToetsingOnline

Brief title

PREOB-NU3

Condition

- Fractures

Synonym

non infected hypotrophic non union fracture - pseudoarthrosis

Research involving

Human

Sponsors and support

Primary sponsor: Bone Therapeutics

Source(s) of monetary or material Support: Bone Therapeutics S.A. (Belgium)

Intervention

Keyword: autologous bone transplant, non-union fractures, osteoblastic cells

Outcome measures

Primary outcome

Clinical symptoms: global disease evaluation using a visual analogue scale;

radiological healing: Radiographic Union Scale for Tibial (RUST) Fracture

extended to all long bones fractures as assessed by CT scan.

Secondary outcome

Clinical symptoms:

- Pain et fracture site at rest, during activities, at palpation using a Visual

Analogue Scale

- Well-being Score (SF12v2)

- Weight-bearing score

Radiological healing: Radiographic Union Scale for Tibial (RUST) Fracture

extended to all long bones fractures as assessed by conventional X-ray.

Tme to bone autograft rescue surgery if applicable (part 1 study only).

Study description

Background summary

Pseudoarthrosis is a bone disorder characterised by a failure of the fracture to heal within 6 months after the fracture occurred. The normal time for fracture healing is about 3 months. Possible causes for pseudoarthrosis can be poor fracture stabilisation or local infection. When these causes are excluded, the reason for this impaired fracture healing seems to be a failure of specific bone cells (called osteoblasts) to multiply. Currently, the most common treatment involves surgery done under general anesthesia during which a piece of bone is taken from the pelvis to be reimplanted directly at the site of the pseudoarthrosis. This treatment also known as autologous bone graft, generates good results but requires major surgery of several hours under general anesthesia, followed by about 4 to 5 days of hospitalisation.

Study objective

To determine the efficacy and the safety of PREOB, a proprietary population of autologous bone-forming cells, in the treatment of non-infected hypotrophic non-union fractures of long bones.

Study design

The study will be performed over two years as a randomised, open, controlled intervention study. A total of 210 patients with non-infected hypotrophic non-union fractures of long bones will be randomized into 2 study arms: 105 patients in the PREOB group and 105 patients in the conservative treatment group. The study will consist of maximum 9 visits and 2 follow-up phone calls.

Intervention

Study part 1:

Study group: percutaneous injection of 2, 3, or 4 ml PREOB suspension (depending on the fracture interline, at a concentration of 4×10^6 cells/ml) using a 3 mm trephine into the fracture site.

Control group: no intervention.

Study part 2:

Study group: percutaneous injection of 2, 3, or 4 ml PREOB suspension (depending on the fracture interline, at a concentration of 4×10^6 cells/ml) using a 3 mm trephine into the fracture site.

Control group: bone autograft surgery following standard of care practices of the centre.

Study burden and risks

A randomised patient will undergo the following procedures during the study:

- 9 blood samples
- 11 x SF-12 questionnaire (also 2x during follow-up period)
- 7 x X-ray of the fracture
- 5 x CT of the fracture

For participating women, a pregnancy test will be performed at each visit.

The burden associated with study participation, besides the standard procedures, lay mainly with the bone marrow and blood sampling.

There is more consulting and medical imaging (X-ray and CT), besides extra lab testing.

The questionnaires patients have to complete, can also be seen as a burden.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

men and women aged between 18 and 65
diagnosed with non-infected hypotrophic non union fractures as confirmed by X-ray

Exclusion criteria

Fracture interline > 1cm
Open fracture with septic local infection
Insufficient fracture stability
osteosynthesis material other than intramedullary nails or plates
bone infection
open fracture
multifocal fracture/ non-union
non-union or non consolidated fracture on the neighbouring bone
nerve damages or tendon lesion at the non-union fracture site

Study design

Design

| | |
|---------------------|-----------------------------|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------|----------------|
| NL | |
| Recruitment status: | Will not start |
| Enrollment: | 49 |
| Type: | Anticipated |

Medical products/devices used

| | |
|---------------|--------------------------|
| Product type: | Medicine |
| Generic name: | Somatic cells autologous |

Ethics review

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|--------------------|--|
| Approved WMO | |
| Date: | 01-11-2012 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Not approved | |
| Date: | 03-01-2013 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|------------------------|
| EudraCT | EUCTR2011-005584-24-NL |
| CCMO | NL41018.000.12 |