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: 28-03-2013
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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	Approved WMO
Status	Will not start
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON41222

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 S.A.
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 Usual

Analogue Scale

-Well-being Score (SF12v2)

- Weight-bearing score

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

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

Study description

Background summary

Pseudoarthrosis is a bone disorder characterised by a failure of the fracture

to heal within 6 months after the fracture occured. 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 176 patients
with non-infected hypotrophic non-union fractures of long bones will be randomized into 2 study arms: 88 patients in the
PREOB group and 88 patients in the bone autograft surgery group. The study will consist of maximum 9 visits and 4 follow-up phone calls.

Intervention

Study group: percutaneous injection of 2,3, or 4 ml PREOB® suspension (depending on the fracture interline, at a concentration of 4 x 10E6 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

- 9 blood samples
- 6 x SF-12 questionnaire (also 4x during follow-up period)
- 6 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

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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 years old
Diagnosed with non-infected hypotrophic non-union fractures as confirmed by X-ray

Exclusion criteria

Fracture interline > 1 cm
Open fracture with septic local infection

Insufficient fracture stability
Osteosynthesis material other than intramedullary nails, scews, plates or external fixation
Bone infection
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:	34
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Approved WMO

Date:	28-03-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	14-08-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-09-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-09-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-01-2015
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-01-2015
Application type:	Amendment
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
ClinicalTrials.gov	NCT01756326
CCMO	NL44005.000.13