Phase III, pivotal, multicentre, randomised, double-blind controlled Study to evaluate the Efficacy and Safety of Autologous Osteoblastic Cells (PREOB®) Implantation in Early Stage Non Traumatic Osteonecrosis of the Femoral Head.

Published: 25-09-2012
Last updated: 26-04-2024

To determine the efficacy and safety of PREOB®, a proprietary population of autologous bone-forming cells, in the treatment of early stage non-traumatic osteonecrosis of the femoral head.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON45063

Source
ToetsingOnline

Brief title
Efficacy and safety of autologous bone transplant for femoral head necrosis

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Nontraumatic osteonecrosis of the femoral head, Tissuedegeneration in femoral head

Research involving
Human

Sponsors and support

Primary sponsor: Bone Therapeutics
Source(s) of monetary or material Support: Bone Therapeutics (Belgium)

Intervention

Keyword: Autologous bone transplant, Early intervention, Femoral head, Osteonecrosis

Outcome measures

Primary outcome

Primary Efficacy Endpoint

- Percentage of treatment responders at Month 24,

a treatment responder at the studied timepoint being defined as a patient who

responded both:

--Clinically, i.e., if at the studied timepoint, the WOMAC® VA3.1 pain

subscale score of the study treated hip improved from baseline by at least the

minimal clinically important difference (MCID),

and

--Radiologically, i.e., if at the studied timepoint, the study treated hip did

not progress to fractural stages (ARCO III or higher), as assessed by

conventional X-ray.

Secondary outcome

- Percentage of treatment responders at Month 6, 12 and 18, and over the

24-month follow-up period

- Percentage of clinical responders at Month 1, 3, 6, 12, 18 and 24, and over

the 24*month follow-up period

- Percentage of radiological responders at Month 6, 12, 18 and 24, and over the

24*month follow-up period

- Absolute change from baseline in WOMAC® VA3.1 total score and composite pain,

stiffness, and function

subscales scores

- Time to hip fracture

- Time to hip arthroplasty

- Percentage of patients requiring hip arthroplasty

Study description

Background summary

Non traumatic osteonecrosis of the femoral head is a disorder that mainly affect young patients (30-60 years old). With the current therapeutic options progression is so severe that nearly half of the patients will need total hip replacement before the age of 40. Previous studies have shown that implantation of autologous bone-marrow cells could lead to improved osteogenesis. Based on these observations, a proprietary cell population of bone-forming cells (PREOB®) has been developed. Phase II has been completed. A phase III clinical study is now needed to confirm the efficacy and safety of PREOB® treatment.

Study objective

To determine the efficacy and safety of PREOB®, a proprietary population of autologous bone-forming cells, in the treatment of early stage non-traumatic osteonecrosis of the femoral head.

Study design

Double-blind placebo controlled intervention study.

Intervention

Study group: Core decompression with a small-diameter trephine and implantation of 5ml PREOB® solution (at concentration of 4*10^6 cells/ml - PREOB®20) into the necrotic lesion.

Control group: Core decompression with a small-diameter trephine and implantation of 5ml Placebo solution into the necrotic lesion.

Study burden and risks

In 9 or 10 visits 5 blood samples will be taken, 8 bilateral questionnaires have to be filled in. 5 or 6 or 5 X-ray of hips (plus one in the occasion confirmation of hip fracture is indicated) and 1 CT will be performed. 4 times bilateral MRI. The associated additional patient load beside the standard procedure (core decompression, medical imaging, laboratory lag and questionnaire) will be the bone marrow harvesting (or sham procedure) and blood harvesting. 3 times additional consultation + bilateral (except for prosthesis) medical imaging (X-ray and MRI) + laboratory and questionnaire for this trial.

Contacts

Public
Bone Therapeutics

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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 18 to 70 years old, diagnosed with:
- an ARCO stage I osteonecrosis with the sum of coronal and sagittal necrotic angles superior to 190 degrees which is symptomatic (pain * 20 mm on the WOMAC® VA3.1 pain subscale during the 48 hours preceding the screening)
- an ARCO stage II osteonecrosis with the sum of coronal and sagittal necrotic angles superior to 190 degrees which can be either symptomatic or asymptomatic
- an ARCO stage II osteonecrosis with the sum of coronal and sagittal necrotic angles inferior to 190 degrees which is symptomatic (pain * 20 mm on the WOMAC® VA3.1 pain subscale during the 48 hours preceding)

Exclusion criteria

ARCO stage III and IV osteonecrosis of the femoral head on the hip which is evaluated, and confirmed by conventional X-ray and and MRI of the hip.
Osteoarthritis on the hip. Bone fracture that might interfere with study evaluation.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2014
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Approved WMO Date:	25-09-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-10-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-10-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-11-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-11-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-01-2014
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:	27-01-2015
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-02-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-04-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	06-07-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-03-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-04-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-06-2018
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	EUCTR2009-012929-11-NL

Register	ID
ClinicalTrials.gov	NCT01529008
CCMO	NL29848.000.12

Study results

Results posted: 03-07-2020

Summary results
Trial ended prematurely

First publication
26-06-2020