

A phase III clinical trial for the two months safety and efficacy evaluation of Ostem™ (autologous cultured osteoblasts) in patients with fracture

Submission date 14/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/05/2008	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

03OST/014

Study information

Scientific Title

A multicentre, randomised and comparative clinical study of the efficacy and safety of Ostem™ (autologous cultured osteoblasts) injection to treat fractures

Study objectives

To accelerate fracture healing, ultrasound and other diverse treatment methods have recently been introduced. In particular, cell therapy suggests a new treatment approach. When using Ostem™ (autologous cultured osteoblasts) rather than bone grafts, problems may develop in the donor area in general autologous bone grafts and immunological problems may develop in allograft, although problems involving the spread of disease are less frequent and a faster patient recovery may be achieved when using Ostem™ (autologous cultured osteoblasts).

The hypothesis for this trial is that patients who implant Ostem™ (autologous cultured osteoblasts) will improve.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the following institutional review boards:

1. Catholic University College of Medicine (Uijeongbu St. Marys Hospital) on 9th March 2006 (ref: UCMC06MT001)
2. Yonsei University College of Medicine on 13th December 2006 (ref: 3-2006-0066)
3. Catholic University College of Medicine (St. Pauls Hospital) on 5th December 2006 (ref: PCMC06MT011)
4. Inje University College of Medicine on 29th December 2006 (ref: 06-33)
5. Dankook University College of Medicine on 22th January 2007 (ref: 2006-36)
6. Konyang University College of Medicine on 24th January 2007 (ref: 06-17)
7. Catholic University College of Medicine (Kangnam St. Marys Hospital) on 16th May 2007 (ref: KCMC06Mt174)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Long bone fracture

Interventions

All patients will receive standardised first fracture surgery (closed or open reduction). At enrolment patients are randomised to receive either injection (intervention group) or observation (control group).

Intervention group: approximately eight weeks after the first open or closed reduction, this group will receive Ostem™ (autologous cultured osteoblasts)

Control group: approximately eight weeks after the first open or closed reduction, this group will be observed but no other treatments performed.

Total duration of follow-up for both treatment arms is two months.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Ostem™ (autologous cultured osteoblasts)

Primary outcome measure

Difference of Callus Formation Score for two months after autologous cultured osteoblast injection.

Secondary outcome measures

No secondary outcome measures

Overall study start date

13/05/2006

Completion date

30/01/2008

Eligibility**Key inclusion criteria**

1. Long bone fracture (femur, tibia, radius, ulna, humerus) patients
2. Aged 15 and 65 years, either sex
3. Approximately six weeks after the first open or closed reduction, the score of callus formation was lower than 3 points
4. Individuals who have completed a written consent form

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

77

Key exclusion criteria

1. Patient who is oversensitive to bovine protein
2. Patients with a known history of anaphylaxis to gentamicin
3. Patients with acute infection in bone defects
4. Patients who have communicable disease (positive reaction against human immunodeficiency virus [HIV], hepatitis C virus [HCV], hepatitis B virus [HBV], cytomegalovirus [CMV], syphilis, human T-lymphotropic virus [HTLV])
5. Patients diagnosed by the investigators to have psychological disorders
6. Patients whose score of callus formation was higher than 4 points

Date of first enrolment

13/05/2006

Date of final enrolment

30/01/2008

Locations

Countries of recruitment

Korea, South

Study participating centre

Catholic University College of Medicine

Uijeongbu

Korea, South

480-717

Sponsor information

Organisation

Individual sponsor (South Korea)

Sponsor details

c/o Ms Su-Young Lee
802 Wooyoung Techno Center, 273-15
Seongsu 2ga 3-Dong
Seongdong-Gu
Seoul
Korea, South
133-831

Sponsor type

Other

Funder(s)

Funder type

Industry

Funder Name

SEWON Cellontech Co., Ltd (South Korea)

Funder Name

Korea Health Industry Development Institute (KHIDI) (South Korea) (ref : A04-0012)

Alternative Name(s)

KHIDI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration