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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/05/2008	**Overall study status** Completed	
Last Edited 22/05/2008	**Condition category** Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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802 Wooyoung Techno Center, 273-15
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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