

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

<b>Submission date</b> 14/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/05/2008	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

No secondary outcome measures

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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)

## **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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration