

# Treatment of early stage osteonecrosis of the femoral head with implantation of autologous bone marrow-derived and cultured mesenchymal stem cells

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<b>Registration date</b> 09/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/02/2010	<b>Condition category</b> Musculoskeletal Diseases	<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

CD-BMMSC-04

# Study information

## Scientific Title

Treatment of early stage osteonecrosis of the femoral head with implantation of autologous bone marrow-derived and cultured mesenchymal stem cells: a single centre randomised controlled interventional trial

## Acronym

CD-BMMSC treatment

## Study objectives

Bone marrow-derived mesenchymal stem cell implantation into the femoral head is effective in treating early stage osteonecrosis of the femoral head, and the number of these mesenchymal stem cells implanted is crucial to the clinical outcome. The hypothesis of this study is to isolate bone marrow mesenchymal stem cells and grow them in vitro to obtain greater number of such cells for femoral head implantation, in order to achieve better clinical outcome.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the Public Health Bureau, the City of Dalian, and the State FDA, China in 2002 (ref: 02-88), 2005 (ref: 05-183) and 2008 (ref: 08-179)

## Study design

Single centre randomised controlled interventional 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

Osteonecrosis of the femoral head at early stage

## Interventions

Osteonecrosis of the femoral head remains a significant health concern. Currently, core decompression combined with implantation of autologous bone marrow mononuclear cells

appears to be an effective treatment against this disease in the early stage. Among the bone marrow mononuclear cells, mesenchymal stem cells (MSCs) are crucial to the efficacy. The number of mesenchymal stem cells (MSCs) in the bone marrow mononuclear cells is very limited, which are crucial to the efficacy of the treatment. Therefore, the aim of our trial is to obtain greater number of bone marrow MSCs through culturing bone marrow-derived mesenchymal stem cells in vitro, and transplant these cultured bone marrow MSCs into the affected femoral head following the procedure of core decompression. In our procedure, about two million cultured bone marrow MSCs could be implanted into the femoral head, compared with that about 20 - 25 thousand MSCs implanted into the femoral head in the procedure employed by other groups, therefore, we expect our procedure could lead to higher clinical and radiographic success rate and better clinical outcome.

Procedure:

1. Isolate mesenchymal stem cells from the autologous bone marrow mononuclear cells
2. The patients are treated with core decompression
3. The cultured stem cells are injected into the femoral head

The duration of our treatment is about 2 weeks. Bone marrow aspiration is performed in the same day of the surgery core decompression, then autologous bone marrow-derived and cultured mesenchymal stem cells are transplanted into the femoral head two weeks post-operatively.

The patient enrolment period was designed from 04 March 2004 to 01 September 2011. Our first manuscript will report the outcome by the 30-month follow-up. We will keep following up the patients as long as we can, at least for 8 years.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Clinical outcome, assessed by the Harris Hip Score, measured pre-operatively and at 3 months, 6 months, 12 months, 30 months, and every 2 years post-operatively thereafter

### **Secondary outcome measures**

Radiographic approaches are used to determine the progress in osteonecrotic stage and to assess the volume of the necrotic lesion in the femoral head, measured pre-operatively and at 3 months, 6 months, 12 months, 30 months, and every 2 years post-operatively thereafter

### **Overall study start date**

04/03/2004

### **Completion date**

01/09/2011

## **Eligibility**

### **Key inclusion criteria**

1. Aged between 18 to 45 years, either sex
2. Patients with hips at stages IC to IIC according to Association Research Circulation Osseous (ARCO) classification
3. Etiological factors including trauma, alcohol abuse, corticosteroid use, Caisson disease, hyperlipidemia, and idiopathic

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

At least 100 patients

**Key exclusion criteria**

1. Pregnancy
2. Current and previous infection
3. Skeletal immaturity
4. Immunosuppressive drug therapy
5. A history of inflammatory arthritis
6. Evidence of cardiovascular diseases
7. Prior systemic corticosteroid treatment
8. Mental health problems preventing adequate follow-up

**Date of first enrolment**

04/03/2004

**Date of final enrolment**

01/09/2011

**Locations****Countries of recruitment**

China

**Study participating centre**

No. 6 Jiefang St.

Dalian

China

116001

# Sponsor information

## Organisation

Dalian University Zhongshan Hospital (China)

## Sponsor details

c/o Dewei Zhao

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.dlhospital.com/yygk/yyjsyw.htm>

## ROR

<https://ror.org/041ts2d40>

# Funder(s)

## Funder type

Government

## Funder Name

China National Natural Science Foundation (China) (ref: grant 30471752 and 30670542)

# 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

