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# 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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| **Submission date**<br>29/01/2010 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>09/02/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/02/2010 | **Condition category**<br>Musculoskeletal Diseases | |

**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**
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 morrow 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
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116001

# Sponsor information

### Organisation
Dalian University Zhongshan Hospital (China)

### Sponsor details
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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