

# Unravelling the cell subsets of osteonecrosis of the femoral head

<b>Submission date</b> 06/02/2026	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/02/2026	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Osteonecrosis of the femoral head (ONFH) is a progressive, disabling disease that often occurs in young and middle-aged populations and severely affects patients' quality of life. However, heterogeneity of subchondral bone cell types present in ONFH is still unknown. Single cell RNA sequencing (scRNAseq) technology can show detailed examination of cellular and molecular diversity. The aim of this study is to identify all major cell populations and immune microenvironment interaction in patients with ONFH using scRNA-Seq.

### Who can participate?

Adults aged between 20 and 65 years with ONFH undergoing THA surgery in our hospital  
And control group: Patients with femoral neck fracture or hip osteoarthritis undergoing THA surgery in our hospital

### What does the study involve?

This is a non-interventional, biological specimen research study. It involves the use of hip joint tissues that are routinely removed and discarded during standard total hip arthroplasty surgery from ONFH, OA or femoral neck fracture. The collected tissues will be processed in the laboratory for single-cell RNA sequencing, histological analysis, and/or molecular biology experiments to investigate disease mechanisms. No further contact or procedures with the participant are required. All tissue samples and data will be de-identified.

### What are the possible benefits and risks of participating?

Participants will receive no direct medical benefit from this research, as the hip joint tissues are surgical discards and the research procedures are performed after the standard therapeutic surgery is complete.

### Where is the study run from?

The study is conducted at Luoyang Orthopedic Hospital of Henan Province, Orthopedic Hospital of Henan Province, Luoyang, Henan, China.

### When is the study starting and how long is it expected to run for?

January 2026 to October 2026

Who is funding the study?  
Administration of Traditional Chinese Medicine of Henan Province (Grant No. 2025ZY1023)  
(China)

Who is the main contact?  
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## **Additional identifiers**

## **Study information**

### **Scientific Title**

Cellular dissection of the bone immune microenvironment in osteonecrosis of the femoral head

### **Study objectives**

The aim of this study is to clarify the changes in the number and function of early immune cell subsets in patients with ONFH and the interaction between multiple different cell subsets at an overall level.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 14/10/2025, Ethics Committee of Luoyang Orthopedic Hospital of Henan Province (No. 82, Qiming South Road, Luoyang, 471002, China; +86 379-63546181; hnslyzgylywh@aliyun.com), ref: the Project of TCM research in Henan Province (Grant No.2025KYKT0039-01)

### **Primary study design**

Observational

### **Secondary study design**

Descriptive observational study

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

### **Health condition(s) or problem(s) studied**

Patients with glucocorticoid-induced osteonecrosis of the femoral head

### **Interventions**

This is a non-interventional, biological specimen research study. It involves the use of hip joint tissues that are routinely removed and discarded during standard total hip arthroplasty surgery from ONFH, OA or femoral neck fracture. The collected tissues will be processed in the laboratory for single-cell RNA sequencing, histological analysis, and/or molecular biology experiments to investigate disease mechanisms. No further contact or procedures with the participant are required. All tissue samples and data will be de-identified.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. Differential Cell Cluster Annotation in necrotic femoral head tissue measured using single cell RNA sequencing at Intraoperative
2. Spatial density of different cell types in the osteonecrosis interface zone measured using Immunohistochemistry and Immunofluorescence at Intraoperative

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

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

1. Experimental group: Patients with femoral head necrosis undergoing THA surgery in our hospital
2. Control group: Patients with femoral neck fracture or hip osteoarthritis undergoing THA surgery in our hospital
3. Willingness to participate in the study and provision of signed informed consent.

### **Healthy volunteers allowed**

Yes

### **Age group**

Mixed

### **Lower age limit**

20 years

### **Upper age limit**

65 years

### **Sex**

All

### **Total final enrolment**

0

### **Key exclusion criteria**

1. Patients with unclear diagnosis
2. Issues with sample quality: Biological samples with severe contamination or other problems during collection, transportation or preservation, which may affect the accuracy of experimental test results. Samples with insufficient quantity to meet the requirements of experimental detection, making them unsuitable for IHC assays.
3. Special populations and other conditions: Pregnant or lactating women.
4. Patients who have recently (within one month) used drugs that may affect experimental results.

5. Patients with severe systemic diseases such as heart, liver or kidney diseases, or those with mental illnesses, malignant tumors or other diseases that may affect research results or life expectancy.

**Date of first enrolment**

23/01/2026

**Date of final enrolment**

31/05/2026

## **Locations**

**Countries of recruitment**

China

## **Sponsor information**

**Organisation**

Luoyang Orthopedic Hospital of Henan Province, Orthopedic Hospital of Henan Province

## **Funder(s)**

**Funder type**

**Funder Name**

Administration of Traditional Chinese Medicine of Henan Province (Grant No. 2025ZY1023)

## **Results and Publications**

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

**IPD sharing plan summary**

Not expected to be made available