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Unravelling the cell subsets of osteonecrosis of the femoral head

Submission date 06/02/2026	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 10/02/2026	**Overall study status** Ongoing	
Last Edited 09/02/2026	**Condition category** Musculoskeletal Diseases	

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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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; hnslyzgyyllywh@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 Immunohistochemisty 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