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Electroacupuncture for pain relief in patients with osteonecrosis of the femoral head: a randomized controlled trial

Submission date
02/09/2025

Recruitment status
No longer recruiting

Registration date
11/09/2025

Overall study status
Completed

Last Edited
10/03/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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. Pain is the core symptom of ONFH. Electroacupuncture, a traditional Chinese medicine therapy, shows potential in chronic pain management, but its effectiveness in relieving ONFH pain is not yet supported by high-quality evidence. The aim of this study is to clarify the effectiveness and safety of electroacupuncture in managing pain in patients with ONFH.

Who can participate?
Adults aged between 20 and 65 years with ONFH who experience hip pain

What does the study involve?
Participants will be randomly assigned to receive either real electroacupuncture or sham electroacupuncture. Each session will last 30 minutes, two times per week, for 4 weeks. Assessments of pain, hip function, psychological status, quality of life, and target hip pain sensitization testing will be conducted before and after the intervention. Safety will be assessed by monitoring adverse events throughout the study.

What are the possible benefits and risks of participating?
Participants may have less hip pain, better joint function, and improved quality of life. All participants will receive medical assessment and monitoring, and the study may help improve treatment options for future ONFH patients.
Minor side effects may include fainting, slight bleeding, local infection, or skin allergy. There may also be unknown risks, and the treatment may not work for all participants. If ineffective, the study doctor may recommend stopping and using other treatments.

Where is the study run from?
The study is conducted at Luoyang Orthopedic Hospital of Henan Province (Orthopedic Hospital of Henan Province), Luoyang, Henan Province, China.

When is the study starting and how long is it expected to run for?
April 2025 to May 2026

Who is funding the study?
This study is funded by 2019 Henan Province Project for Basic Evidence-Based Capacity Building in Traditional Chinese Medicine (Luoyang Orthopedic Hospital of Henan Province) (China)

Who is the main contact?
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Additional identifiers

Protocol serial number
2025ZXKT0001-02

Study information

Scientific Title
Effects of electroacupuncture on pain changes in patients with osteonecrosis of the femoral head: a randomized, triple-blind, sham-controlled, parallel-group study

Study objectives
The aim of this study is to clarify the efficacy and safety of electroacupuncture in managing pain in patients with osteonecrosis of the femoral head (ONFH) by a randomized controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/07/2025, Ethics Committee of Luoyang Orthopedic Hospital of Henan Province (No. 82, Qiming South Road, Luoyang, 471002, China; +86 (0)379-63546181; hnslyzgyyllywh@aliyun.con), ref: 2025ZXKT0001-02

Primary study design
Interventional

Study design
Randomized triple-blind sham-controlled parallel-group study

Study type(s)
Efficacy, Quality of life, Safety, Treatment

Health condition(s) or problem(s) studied
Osteonecrosis of the femoral head

Interventions
Participants in both the trial and control groups will receive treatment at the same frequency and duration: twice per week with a 2–3-day interval between sessions, over a period of 4 weeks, for a total of 8 sessions.

Based on meridian differentiation in Traditional Chinese Medicine and clinical experience, a consensus will be reached on the selection of proximal and distal acupoints. The selected acupoints will include both primary and supplementary points. Primary acupoints will consist of

Huantiao (GB30), Juliao (GB29), Biguan (ST31), Zhibian (BL54), and one Ashi point (the most painful site identified by the patient). In addition, a supplementary acupoint will be selected according to the location of hip pain: Liangqiu (ST34) for anterior hip pain, Xuehai (SP10) for medial pain, Weizhong (BL40) for posterior pain, and Yanglingquan (GB34) for lateral hip pain.

Participants will be placed in the healthy-side lateral decubitus position. Following routine disinfection, disposable sterile acupuncture needles (Pingbing type; sizes: 0.35×40 mm and 0.35 ×75 mm; Womeda Medical Device Technology Co., Ltd., Suzhou) will be inserted into the designated acupoints to a depth of 30–45 mm. EA equipment will adopt the HANS acupoint nerve stimulator (model HANS-200E, produced by Nanjing Jisheng Medical Technology Co., Ltd.). The output electrodes will be connected to the handles of the inserted needles. A sparse-dense wave mode at 2/100 Hz will be applied, with current intensity adjusted according to each participant's tolerance. The needles will be retained for 30 minutes per session.

Sham electroacupuncture will be applied at non-acupoint locations about 20 mm away from the real acupoints, avoiding meridians and known acupuncture points. Sterile, disposable acupuncture needles of the same specifications will be inserted superficially to a depth of approximately 3-5 mm. Electroacupuncture device identical in appearance and model to that used in the intervention group will be connected using specially customized lead wires that contain no internal conductors, thereby preventing any current output.

To maintain blinding, acupuncturists will turn on the device during treatment to ensure visual and auditory cues (e.g., indicator lights and beeping sounds) are consistent with the real intervention. The electroacupuncture parameters and needle retention time will be the same as in the intervention group. Additionally, acupuncturists will perform a standardized mock stimulation procedure to best simulate the real treatment scenario, following these steps: 1) Attach the lead clips to the needle handles and set the frequency to 2/100 Hz; 2) Inform the participant that the device is being turned on; 3) Ask whether the participant feels comfortable and able to tolerate the 25–30-minute session; 4) If the participant questions the lack of sensation, the acupuncturist will explain that in this "special type of acupuncture," the stimulation may fall below the sensory threshold and thus may no.

All treatments will be performed by licensed TCM practitioners with a minimum of five years of clinical experience. All acupuncturists will receive standardized operating procedure (SOP) training prior to the study to ensure procedural consistency and treatment safety.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The proportion of participants with a clinically meaningful reduction in pain at the end of treatment (Week 4 ± 1 day). A clinically meaningful reduction is defined as a decrease of ≥20 mm or ≥33% from baseline on a 0–100 mm Visual Analog Scale (VAS).

Key secondary outcome(s)
1. Pain intensity measured using the 0–100 mm VAS score at baseline, Week 4, Week 8, Week 12, and Week 16.
2. The proportion of participants achieving clinically significant pain improvement (≥20 mm or ≥33% reduction from baseline on the 0–100 mm VAS score, calculated from raw VAS data) at Week 8, Week 12, and Week 16.
3. Function of the target hip evaluated using the modified Harris Hip Score (mHHS) at baseline,

Week 4, Week 8, Week 12, and Week 16.
4. Pain sensitization assessed through Pressure Pain Threshold (PPT) and Temporal Summation (TS) testing at baseline, Week 4, Week 8, Week 12, and Week 16.
5. Psychological status, assessed using validated questionnaires at baseline, Week 4, Week 8, Week 12, and Week 16:
5.1. Depression severity measured using the Patient Health Questionnaire-9 (PHQ-9).
5.2. Anxiety symptoms measured using the Generalized Anxiety Disorder-7 (GAD-7).
5.3. Pain-related cognitive-emotional exaggeration measured using the Pain Catastrophizing Scale (PCS).
5.4. Confidence in managing pain measured using the Pain Self-Efficacy Questionnaire (PSEQ).
6. Health-related quality of life evaluated using the 12-item Short Form Health Survey (SF-12) at baseline, Week 4, Week 8, Week 12, and Week 16.

Added 17/09/2025:
7. Frequency of rescue analgesic medication use: The frequency and dosage of analgesic medication (Celecoxib) taken by participants will be recorded. Data will be collected at 4 weeks, 8 weeks, 12 weeks, and 16 weeks.
8. Incidence of adverse events (AEs): The number and proportion of participants experiencing adverse events (e.g., dizziness, local pain at the needling site, bleeding, and, in rare cases, infection or skin irritation) will be recorded. Safety data will be monitored continuously and summarized at 4 weeks, 8 weeks, 12 weeks, and 16 weeks. Causality with the intervention will be assessed by the investigators.

Completion date
07/05/2026

Eligibility

Key inclusion criteria
1. Meet the diagnostic criteria for ONFH
2. Aged between 20 and 65 years, inclusive
3. No surgery anticipated or planned within the next 4 months
4. History of ONFH-related pain persisting for more than 3 months
5. Target hip visual analog scale (VAS) score ≥40 mm, with the contralateral hip score being lower than that of the target hip. The target hip is defined as the affected side in cases of unilateral ONFH, and as the hip with the higher pre-randomization VAS score in bilateral ONFH
6. Willingness to participate in the study and provision of signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 Years

Upper age limit

65 Years

Sex
All

Total final enrolment
176

Key exclusion criteria
1. Presence of systemic or local conditions that may interfere with the assessment of ONFH-related pain or hip function, including systemic joint disorders (e.g., rheumatoid arthritis), chronic inflammatory or connective tissue diseases, other hip pathologies (e.g., developmental dysplasia of the hip), lumbar spine disorders (e.g., lumbar disc herniation), or any other condition that may impact efficacy evaluation
2. Combination of serious organic diseases (e.g., serious cardiovascular and cerebrovascular diseases, tumors), diagnosed psychiatric disorders (e.g., anxiety disorders), or intellectual disability
3. Previous experience with EA for any indication
4. History of total hip arthroplasty on the affected side, or any surgical intervention on the target hip (e.g., hip-preserving surgery) within 12 months prior to screening
5. Any acupuncture-related therapy (e.g., acupuncture, moxibustion) or shockwave therapy applied to the target hip within 3 months before screening
6. History of invasive interventions (e.g., intra-articular injection) to the target hip within 6 months prior to screening
7. Pregnant or lactating women, or women planning to conceive within the next 4 months
8. Known or suspected history of needle syncope (needle phobia)
9. Known or suspected metal allergy
10. Currently undergoing corticosteroid treatment

Date of first enrolment
23/09/2025

Date of final enrolment
07/01/2026

Locations

Countries of recruitment
China

Study participating centre
Luoyang Orthopedic Hospital of Henan Province (Orthopedic Hospital of Henan Province)
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Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type
Government

Funder Name
Henan Provincial Department of Finance

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Li Zhipeng (lizhipeng20212021@163.com).
Shared data will include de-identified individual participant data collected during the study. Data will become available after publication and for at least 5 years. Requests will be considered for legitimate scientific purposes, subject to approval by the corresponding author to ensure compliance with participant consent and ethical requirements. Data will be anonymized prior to sharing to protect confidentiality.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/03/2026	10/03/2026	Yes	No