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Study on the effectiveness of auricular acupressure in improving sleep after knee surgery

Submission date
02/04/2025

Recruitment status
No longer recruiting

Registration date
03/04/2025

Overall study status
Completed

Last Edited
03/04/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to assess the effectiveness and safety of auricular acupressure (AA) therapy in improving postoperative sleep quality in patients undergoing total knee arthroplasty (TKA), a surgical procedure to replace a damaged knee joint with artificial components. Postoperative sleep disorders are common after TKA and can hinder recovery. By exploring auricular acupressure, this study investigates a non-pharmacological intervention to alleviate sleep disturbances and improve recovery outcomes.

Who can participate?
Patients aged 50 years or older, diagnosed with knee osteoarthritis and scheduled for unilateral TKA

What does the study involve?
Participants will be randomly assigned to either the auricular acupressure (AA) group or the sham auricular acupressure (SAA) group. Both groups will receive similar treatments, but only the AA group will receive active auricular acupressure therapy, which involves the stimulation of specific points on the ear. The study involves assessments of sleep quality, pain levels, and biomarkers such as melatonin and CRP before and after surgery. The intervention will be administered on the day of surgery, with follow-up for 5 days after surgery.

What are the possible benefits and risks of participating?
Possible benefits include improved sleep quality, reduced pain, and enhanced recovery due to decreased inflammation. The risks are minimal and may include minor discomfort at the acupressure points, such as mild ear pain or skin irritation. No serious adverse events related to the intervention have been observed so far. Participants will be closely monitored for any side effects.

Where is the study run from?
Hefei First People's Hospital (China)

When is the study starting and how long is it expected to run for?
June 2024 to March 2025

Who is funding the study?
This work was supported by Grants from the Health Research Project of Health Commission of Anhui Province (No. AHWJ2024Aa30021), the Hefei Municipal Natural Science Foundation (HZR2444), the Key Project of Health Commission Applied Medical Research of Hefei (Hwk2024zd011), the Basic and Clinical Collaborative Research Promotion Initiative of the Third Affiliated Hospital of Anhui Medical University (2022sfy007).

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HZR2444/Hwk2024zd001/No. AHWJ2024Aa30021

Study information

Scientific Title

Effectiveness and safety of auricular acupressure therapy for postoperative sleep disorders following total knee arthroplasty: a randomized controlled trial comparing auricular acupressure to sham auricular acupressure

Study objectives
Auricular acupressure (AA) can significantly improve postoperative sleep quality and reduce the incidence of postoperative sleep disorders in patients undergoing total knee arthroplasty (TKA).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/11/2024, Ethics Committee of The First People's Hospital of Hefei (No. 390 Huaihe Road, First People's Hospital of Hefei, Hefei, 230000, China; +86 (0)551-82137855; hfyykjcyc@126.com), ref: 2024-278-02

Study design
Single-center interventional randomized double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Postoperative sleep quality in TKA patients

Interventions
Randomization and allocation concealment were implemented strictly. A random number table was generated using IBM SPSS version 26.0 to assign participants in a 1:1 ratio to either the Sham Auricular Acupressure (SAA) group or the Auricular Acupressure (AA) group. The treatment assignments were sealed in sequentially numbered, opaque envelopes. An independent physician opened the envelope upon patient admission and informed the nursing staff to arrange the corresponding intervention, thereby achieving allocation concealment. Outcome assessors, data collectors, and statistical analysts were not involved in the intervention procedures and remained blinded to group assignments. Participants were also blinded throughout the study, creating a double-blind environment.

Both groups received standardized anesthesia and postoperative intravenous analgesia protocols. Auricular acupressure interventions were administered at 7:00 AM on the day of surgery by the same licensed acupuncturist with a mid-level professional qualification. In the AA group, six specific auricular acupoints - Shenmen (TF4), Sympathetic (AH6), Endocrine (CO18), Heart (CO15), Liver (CO12), and Kidney (CO10) - were identified using a metal probe. After disinfection with alcohol, adhesive patches containing Vaccaria seeds were applied to the targeted points. In the SAA group, blank adhesive tape of a similar color was used to cover the same acupoints. Following the intervention, all patients were instructed to press each taped point 4–5 times per day, for 3–5 minutes per session, over a period of 7 consecutive days. All procedures were standardized, and the acupuncturist did not have further contact with the patients after completing the intervention in order to prevent potential bias from additional interaction.

Intervention Type
Other

Primary outcome measure
1. Subjective sleep quality assessed using the Insomnia Severity Index (ISI), with scores ranging from 0 to 28. Higher scores indicate poorer sleep quality and more severe insomnia symptoms. Assessment time points included 1 day before surgery, and postoperative days 0 (day of surgery), 1, 3, and 5. All assessments were conducted at 7:00 AM on the morning following each designated time point.
2. Salivary melatonin levels measured using enzyme-linked immunosorbent assay (ELISA). Saliva samples (0.5 ml) were collected at 9:00 PM on the evening of 1 day before surgery, the day of surgery, and postoperative days 1, 3, and 5. Immediately after collection, samples were centrifuged, and the supernatant was separated and stored at −80°C for subsequent analysis.

Secondary outcome measures
1. Pain assessed using a standardized dynamic monitoring protocol, Visual Analog Scale (VAS) Score, at the following timepoints: 1 day prior to surgery, 6 hours postoperatively, and on postoperative days 1, 3, and 5. Pain intensity was evaluated under two physiological conditions: (1) at rest; and (2) during functional activity, using a standardized 5-meter walking test.
2. Serum C-reactive protein (CRP) levels measured using blood samples collected at 24 hours before surgery and at 24 and 72 hours postoperatively. All samples were sent to the institutional laboratory for analysis. CRP levels were determined using an immunoturbidimetric assay.
3. Additional administration of sedative drugs: When patients reported difficulty falling asleep at night, they were first instructed to perform auricular acupoint stimulation. If sleep initiation remained unsuccessful and the patient expressed a strong need for pharmacological assistance, the night-shift assessor administered 5 mg of estazolam to aid sleep. The number of patients in each group who required sedative medication was carefully recorded for subsequent data analysis.
4. Adverse events were monitored and recorded throughout the treatment period in both groups. These included occurrences of nausea, dizziness, ear pain, numbness, infection, and allergic reactions related to the intervention. In addition, postoperative knee-related complications were also monitored, including periprosthetic joint infection, deep vein thrombosis (DVT) in the lower limbs, and knee joint stiffness.

Overall study start date
01/06/2024

Completion date
15/03/2025

Eligibility

Key inclusion criteria
1. Age ≥50 years
2. Diagnosis of knee osteoarthritis according to the criteria established by the International Society of Rheumatology
3. Scheduled to undergo unilateral TKA
4. Educational level of at least completion of compulsory primary education

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
107

Total final enrolment
88

Key exclusion criteria
1. Presence of psychiatric disorders such as delirium, dementia, or other cognitive impairments
2. Peripheral nervous system injury or other musculoskeletal injuries
3. History of myocardial infarction or other severe cardiovascular diseases within the past 12 months
4. History of Raynaud’s disease
5. Active vasculitis or severe peripheral vascular disease
6. History of periprosthetic joint infection around the knee
7. History of substance abuse or drug dependence
8. Acupuncture-related phobia or aversion
9. Any other conditions deemed unsuitable for participation in clinical research by the investigators

Date of first enrolment
25/10/2024

Date of final enrolment

05/03/2025

Locations

Countries of recruitment
China

Study participating centre
The First People's Hospital of Hefei
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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name

Health Research Project of Health Commission of Anhui Province

Funder Name
Hefei Municipal Natural Science Foundation

Funder Name
Key Project of Health Commission Applied Medical Research of Hefei

Funder Name
Basic and Clinical Collaborative Research Promotion Initiative of the Third Affiliated Hospital of Anhui Medical University

Results and Publications

Publication and dissemination plan
Planned for publication in a peer-reviewed journal

Intention to publish date
01/08/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date