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The effect of a bracelet on gastrointestinal recovery after unicompartmental knee arthroplasty

Submission date 06/11/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 20/01/2025	**Overall study status** Ongoing	
Last Edited 09/10/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

With the increasing ageing population, the incidence of knee joint degeneration is increasing year by year. Unicompartmental knee arthroplasty (UKA) is surgery used to treat end-stage knee joint diseases, which can significantly relieve pain and correct deformity. Postoperative nausea and vomiting (PONV) and constipation are common complications of UKA. Therefore, reducing the incidence of nausea and vomiting is the focus of attention and research at present. Transcutaneous electrical acupoint stimulation (TEAS) via a wearable EmeTerm® bracelet at the Neiguan (PC6) acupoint is a non-invasive approach that can reduce the incidence of PONV, but it has not been studied in the setting of unicompartmental knee arthroplasty. This study therefore aims to evaluate the effect of the EmeTerm® bracelet on PONV and constipation after UKA.

Who can participate?

Patients aged 50 – 75 years with end-stage medial compartment knee osteoarthritis who are scheduled for primary unilateral unicompartmental knee arthroplasty

What does the study involve?

Participants are randomly assigned to receive active stimulation with the EmeTerm® bracelet or sham (device off) at identical time points. PONV is recorded within 24 hours after surgery (assessed at 6, 12, and 24 hours); constipation, bowel recovery, and adverse events are followed at 72 hours or discharge.

What are the possible benefits and risks of participating?

Possible risks of the surgery include deep venous thrombosis, knee joint stiffness, and acute knee infection. The benefits of participation include a better understanding of the effect of the bracelet on postoperative PONV after joint replacement.

Where is the study run from?

Luoyang Orthopedic Hospital of Henan Province, Orthopedic Hospital of Henan Province (China)

When is the study starting and how long is it expected to run for?
January 2025 to December 2027

Who is funding the study?
1. Post-doctoral research funding project in Henan Province
2. Heluo Young People Supporting Talents Project
3. Special subject of scientific research of traditional Chinese medicine in Henan Province
4. Start-up funds for doctoral research
5. Project of Science and Technology of Henan Province

Who is the main contact?
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Start-up funds for doctoral research number
2024BS02

Heluo Young People Supporting Talents Project number
2024HLTJ17

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2024ZXKT0009-01, 82104896

Special subject of scientific research of traditional Chinese medicine in Henan Province number
2024ZY3067

Project of Science and Technology of Henan Province number
252102310082

Post-doctoral research funding project in Henan Province number
365154

Study information

Scientific Title
Effects of a wearable transcutaneous electrical acupoint stimulation bracelet on gastrointestinal reactions following unicompartmental knee arthroplasty

Study objectives
This study aims to evaluate the effect of the EmeTerm® bracelet in preventing nausea, vomiting and constipation in patients undergoing unicompartmental knee arthroplasty

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/01/2025, Luoyang Orthopedic Hospital of Henan Province Ethics Committee (82 Qiming South Road, Luoyang, 471000, China; +86 (0)13258289917; hnlc.love@163.com), ref: 2024ZXKT0009-01

Primary study design
Interventional

Study design
Parallel randomized controlled trial

Study type(s)
Efficacy, Prevention, Treatment

Health condition(s) or problem(s) studied
Postoperative nausea, vomiting and constipation in patients undergoing knee replacement

Interventions
Current interventions as of 09/10/2026:
Using an acupoint stimulation bracelet (EmeTerm®), a wearable transcutaneous electrical acupoint stimulation (TEAS) device, worn on the Neiguan (PC6) acupoint. Stimulation is delivered for 30 minutes per session at 30 minutes before anesthesia, immediately after surgery, and every 3 hours until 24 hours after surgery. The control group wears the same bracelet at identical time points with the device switched off (sham stimulation).

Previous interventions:
Using an acupoint stimulation bracelet (EmeTerm®)

All patients received the same perioperative management and drug treatment. The incidence of PONV at different time points (3, 6, 12 and 24 hours after the operation) was measured, and the curative effect of SDZ-V on PONV after the operation was observed and analyzed.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Acupoint stimulation bracelet (EmeTerm®)

Primary outcome(s)
1. The incidence of postoperative nausea and vomiting (PONV) within 24 hours after surgery is measured using a standardized case-report form completed by blinded ward nurses and independent assessors at 6, 12, and 24 hours after surgery

Previous primary outcome as of 09/10/2026:
The incidence of PONV measured using questionnaire at 3, 6, 12 and 24 hours after the operation

Key secondary outcome(s)
1. Severity of nausea and vomiting measured using the Common Terminology Criteria for Adverse Events (CTCAE) v5.0 at 6, 12, and 24 hours after surgery

2. The rate of postoperative nausea and vomiting (PONV) measured using a standardized case-report form at 6, 12, and 24 hours after surgery

3. The rate of antiemetic rescue measured using a case-report form at 24 hours after surgery

4. The postoperative first exhaust time measured using hours from the end of surgery by nurse-recorded assessment with telephone follow-up at 24 hours and at 72 hours (or at discharge if earlier)

5. The postoperative first defecation time measured using hours from the end of surgery by nurse-recorded assessment with telephone follow-up at 24 hours and at 72 hours (or at discharge if earlier)

6. The incidence of postoperative constipation, defined as no defecation within 72 hours or granular/lumpy faeces measured using the Bristol Stool Form Scale (types 1–2) at 72 hours after surgery (or at discharge if earlier)

7. The rate of bracelet-related adverse events measured using a standardized adverse-event form at 6, 12, 24, and 72 hours (or at discharge)

8. Patient satisfaction with gastrointestinal management measured using a 5-point Likert scale at 72 hours after surgery or at discharge

Previous secondary outcomes as of 09/10/2026:
1. The severity of nausea and vomiting measured using questionnaire in the 24 hours after the operation
2. First exhaust time and defecation time after the operation, measured using questionnaire
3. Levels of hemoglobin, albumin and electrolyte in blood measured using hospital monitoring system after the operation
4. The incidence of constipation measured using questionnaire at 3 days after the operation
5. Stratified analysis on the basis of anesthesia method and the risk of nausea and vomiting

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 09/10/2026:
1. Adults aged 50–75 years with end-stage medial compartment knee osteoarthritis;
2. Scheduled for primary unilateral unicompartmental knee arthroplasty;
3. American Society of Anesthesiologists (ASA) physical status I–III;
4. Able to understand and complete the study assessments;
5. Provision of written informed consent.

Previous key inclusion criteria:
1. Patients aged 18 to 75 years who need knee replacement due to end-stage osteoarthritis
2. Patients who voluntarily participate in clinical trials and sign informed consent forms with good compliance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 09/10/2026:
1. Pacemaker, implantable glucose monitor, or cochlear implant;
2. Acupuncture treatment, or use of antiemetics or systemic steroids, within 2 weeks before surgery;
3. Severe hepatic or renal insufficiency;
4. Allergy to metal or study medications;
5. Existing nausea, vomiting, or constipation at screening;
6. Current use of drugs to treat nausea, vomiting, or constipation;
7. History of gastrointestinal surgery or severe gastrointestinal disease affecting bowel function;
8. Participation in another interventional trial.

Previous key exclusion criteria:
1. Patients undergoing revision and bilateral joint replacement
2. Patients who have received acupuncture treatment within 2 weeks
3. Patients with rheumatoid disease, systemic lupus erythematosus and ankylosing spondylitis

4. Patients with severe deformity of knee joint (knee flexion ≥30 degrees, varus ≥30 degrees or valgus ≥15 degrees)
5. severe hepatic and renal insufficiency
6. Patients with central nervous system or mental illness
7. Those who are experiencing nausea, vomiting, diarrhea or constipation, and those who are taking drugs or non-drugs to treat nausea, vomiting, diarrhea or constipation, and those who are taking drugs that affect gastrointestinal motility
8. Skin allergy, breakage, infection or itching at the test site, etc

Date of first enrolment
10/01/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
China

Study participating centre
Luoyang Orthopedic Hospital of Henan Province
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471000

Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type
Government

Funder Name
Post-doctoral research funding project in Henan Province

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Heluo Young People Supporting Talents Project

Funder Name
Special subject of scientific research of traditional Chinese medicine in Henan Province

Funder Name
Start-up funds for doctoral research

Funder Name
Henan Provincial Science and Technology Research Project

Alternative Name(s)
Henan Province Science and Technology Research Project, Henan Science and Technology Research Project, Key Project of Science and Technology of Henan Province, Key Scientific and Technological Research Projects of Henan Province, Project for Science and Technology Plan of Henan Province, Henan Scientific and Technological Research Project,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Guorui Cao, 13688172272@163.com

IPD sharing plan summary
Available on request