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

Submission date 06/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/01/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 20/01/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

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. The application of a non-invasive anti-vertigo bracelet can effectively stimulate relevant acupoints, reduce the incidence of PONV and promote the rehabilitation of patients, but it has not been applied to the research in the field of joint replacement. Therefore, this study intends to verify the effect of a non-invasive anti-vertigo bracelet in preventing knee replacement PONV.

Who can participate?
Patients aged 18 - 75 years who need UKA due to end-stage osteoarthritis

What does the study involve?
All patients received the same perioperative management and drug treatment. The incidence of PONV at different timepoints (3, 6, 12 and 24 hours after the operation) was measured, and the curative effect of the bracelet on PONV after the operation was observed and analyzed.

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 2025

Who is funding the study?
1. National Natural Science Foundation of China
2. Project of Science and Technology of Henan Province (China)

Who is the main contact?
Guorui Cao, 13688172272@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Guorui Cao

Contact details
82 Qiming South Road
Luoyang
China
471000
+86 (0)13258289917
13688172272@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2024ZXKT0009-01, 82104896

Study information

Scientific Title
The effect of EmeTerm® bracelet on gastrointestinal reaction 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

Study design
Parallel randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Prevention, Treatment, Efficacy

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

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

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
Other

Primary outcome measure
The incidence of PONV measured using questionnaire at 3, 6, 12 and 24 hours after the operation

Secondary outcome measures
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

Overall study start date
01/01/2025

Completion date
31/12/2025

Eligibility

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
240

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
30/06/2025

Locations

Countries of recruitment
China

Study participating centre
Luoyang Orthopedic Hospital of Henan Province
82 Qiming South Road
Luoyang
China
610041

Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

Sponsor details
No 82, Qiming South Road
Luoyang
China
471000
+86 (0)15713792777
hnsgkyyhr@126.com

Sponsor type
Hospital/treatment centre

Website
https://www.lyzhenggu.cn/

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

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

Results and Publications

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

Intention to publish date
31/12/2025

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