

The efficacy of the EmeTerm bracelet in preventing postoperative nausea and vomiting

Submission date 10/11/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/10/2024	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Postoperative nausea and vomiting are common complications after total joint arthroplasty. Recent research has shown that the EmeTerm bracelet can safely and effectively reduce the incidence of nausea and vomiting after general surgery. However, there is no research in the field of joint replacement. Therefore, this study will explore the effects of the EmeTerm bracelet in treating nausea and vomiting after total joint arthroplasty.

Who can participate?

Patients at our hospital were eligible for enrollment if they (1) were scheduled for primary unilateral THA or TKA under spinal anesthesia between November 2023 and April 2024 to treat osteoarthritis or other joint diseases at an advanced stage; (2) were between 18 and 75 years old; and (3) scored 2 (moderate risk) or 3-4 (high risk) for PONV on Apfel scale.

What does the study involve?

Patients need to wear the bracelet in a fixed location and at a fixed time. The test group will receive stimulation while the control group will not.

What are the possible benefits and risks of participating?

The possible benefits of this study are less nausea and vomiting after surgery. There are rarely any risks from the bracelets, and the occasional adverse reactions are local skin reactions, including local skin redness, itching, and rash.

Where is the study run from?

Department of Orthopedic Surgery, 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?

March 2023 to February 2024

Who is funding the study?

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

Who is the main contact?
Ms Yang, 709925524@qq.com (China)

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Ms Yi dan Yang

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Risk of postoperative nausea and vomiting after total hip or knee arthroplasty under spinal anesthesia: randomized trial comparing conventional anti-emetics with or without EmeTerm® bracelet

Study objectives

The EmeTerm bracelet is effective in preventing postoperative nausea and vomiting after total joint arthroplasty

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/10/2023, Ethics Committee of Luoyang Orthopedic Hospital of Henan Province. Orthopedic Hospital of Henan Province (No. 82 Qiming South Road, Luoyang City, Henan Province, 471000, China; +86 379 63546181; lyzgl@sina.com), ref: 2023ZXKT0006-01

Study design

single-center interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Efficacy

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied

Prevention of postoperative nausea and vomiting in patients with total joint arthroplasty under spinal anesthesia

Interventions

Current interventions as of 21/10/2024:

Randomization: To enhance the baseline comparability, THA and TKA have been chosen as stratification factors. A researcher who is not involved in subsequent studies will stratify the included patients based on THA and TKA, and use computer-generated random sequences which are put in a sealed envelope to stratify random grouping.

Patients will be divided into a control group and a test group. In the test group, patients will wear the EmeTerm bracelet on both sides of the acupoints named Neiguan (on the palmar side of the forearm, between the proximal end of the wrist striation 3-5cm, between the palmaris longus tendon and the radial wrist flexor tendon), usually at a frequency of 2/10 Hz, to make the patient feel slight numbness on the radial side of the palm, lasting for 30 minutes each time. It is applied once half an hour before anesthesia induction, once after surgery until the ward, and then every 3 hours until the bracelet is removed 24 hours after surgery. In the control group, the anti-dizziness bracelet will be worn at the same time and location, but without stimulation.

Previous interventions:

Randomization: To enhance the baseline comparability, female and motion sickness history have been chosen as stratification factors. A researcher who is not involved in subsequent studies will stratify the included patients based on gender and history of motion sickness, and use computer-generated random sequences which are put in a sealed envelope to stratify random grouping.

Patients will be divided into a control group and a test group. In the test group, patients will wear the EmeTerm bracelet on both sides of the acupoints named Neiguan (on the palmar side of the forearm, between the proximal end of the wrist striation 3-5cm, between the palmaris longus tendon and the radial wrist flexor tendon), usually at a frequency of 2/10 Hz, to make the patient feel slight numbness on the radial side of the palm, lasting for 30 minutes each time. It is applied once half an hour before anesthesia induction, once after surgery until the ward, and then every 3 hours until the bracelet is removed 24 hours after surgery. In the control group, the anti-dizziness bracelet will be worn at the same time and location, but without stimulation.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

EmeTerm ®, Canadian Walter Company, Chinese name Shuleding ®

Primary outcome measure

Current primary outcome measure as of 21/10/2024:

1. The incidence of PONV within 24 h postoperatively

Previous primary outcome measure:

1. The total number and frequency of patients experiencing nausea and vomiting measured using patient records 24 hours after surgery
2. Number and frequency of patients experiencing nausea and vomiting measured using patient records at 0-3, 3-12, and 12-24 hours after surgery
3. The severity of nausea and vomiting measured using patient records 24 hours after surgery

Secondary outcome measures

Current secondary outcome measures as of 21/10/2024:

1. The rates within 24 h postoperatively: complete response of PONV and severe PONV
2. The rate of PONV during different postoperative intervals (0-3 h, 3-6 h, 6-12 h, 12-24 h)
3. The rate of metoclopramide rescue within 24 h postoperatively
4. The rate of bracelet-related adverse events, defined as local allergic reactions on the skin
5. The quality of recovery at 24 and 48 h postoperatively using the 40-item Quality of Recovery (QOR-40) instrument

Previous secondary outcome measures:

1. The usage rate and dosage of postoperative nausea and vomiting remedies measured using patient records 24 hours after surgery
2. The incidence of equipment-related complications measured using patient records 24 hours after surgery

Overall study start date

12/03/2023

Completion date

29/04/2024

Eligibility

Key inclusion criteria

Current inclusion criteria as of 21/10/2024:

Patients at our hospital were eligible for enrollment if they (1) were scheduled for primary unilateral THA or TKA under spinal anesthesia between November 2023 and April 2024 to treat osteoarthritis or other joint diseases at an advanced stage; (2) were between 18 and 75 years old; and (3) scored 2 (moderate risk) or 3-4 (high risk) for PONV on Apfel scale

Previous inclusion criteria:

Patients aged 18-75 who require unilateral and initial total joint arthroplasty due to hip or knee joint disease.

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

140

Total final enrolment

Key exclusion criteria

Current exclusion criteria as of 21/10/2024:

1. Were allergic to metal or study medications
2. Had a pacemaker, implantable glucose monitor, or cochlear implant
3. Had taken anti-emetics or systemic steroids within the previous week
4. Had diabetes and did not show adequate control of blood glucose
5. Suffered severe dysfunction of the heart, kidneys, or liver

Previous exclusion criteria:

1. Cardiac pacemakers, blood glucose meters, or cochlear implants
2. Epilepsy
3. Metal contact allergies
4. Nausea and vomiting within one week before admission
5. Any surgery within one month prior to admission

Date of first enrolment

20/11/2023

Date of final enrolment

26/04/2024

Locations

Countries of recruitment

China

Study participating centre

Department of Orthopedic Surgery, Luoyang Orthopedic Hospital of Henan Province.

Orthopedic Hospital of Henan Province

No. 82 Qiming South Road,

Luoyang City, Henan Province

China

471000

Sponsor information

Organisation

Luoyang Orthopedic-Traumatological Hospital of Henan Province

Sponsor details

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471000
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zggy6354@sina.com

Sponsor type

Hospital/treatment centre

Website

<http://www.lyzhenggu.cn/>

ROR

<https://ror.org/05br7cm44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Ms Yang (709925524@qq.com). Consent will be obtained from participants to share anonymised data. This will be made available subject to a data-sharing agreement. Data will only be shared after there is an appropriate agreement in place and anonymised prior to sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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