ISRCTN60848297 https://doi.org/10.1186/ISRCTN60848297

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

Submission date 10/11/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/11/2023	**Overall study status** Completed	
Last Edited 21/10/2024	**Condition category** Signs and Symptoms	

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
No. 82 Qiming South Road
Luoyang City, Henan Province
China
471000
+86 17839954318
709925524@qq.com

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; lyzgll@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

360

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

Department of Orthopedic Surgery
No. 82 Qiming South Road
Luoyang City, Henan Province
China
471000
+86 0379-63546550
zgyy6354@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?

Participant information sheet	10/11/2023	No	Yes