Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of acupuncture on ear pain, blood parameters, hemodynamic indices, stress, nausea and vomiting in surgical candidates

Protocol summary

Study aim
Effects of acupuncture on ear pain, blood parameters, hemodynamic indices, stress, nausea and vomiting in surgical candidates
Design
This study was a double-blind clinical trial with parallel groups that were randomly divided into control and intervention groups.
Settings and conduct
Patients will be randomly divided into intervention and control groups by random number table. Patients in the intervention group will receive massage for 15 minutes at thalamic point of right ear. It should be noted that the researcher and the data analyst are uninformed and blind in the study. No action will be taken for the control group. All operations will be performed in the hospital.
Participants/Inclusion and exclusion criteria
Inclusion criteria: consent to participate in the study
Exclusion criteria: no ear problems, no ear infections
Intervention groups
Intervention group will receive thalamus point massage in right ear for 15 minutes. The control group will not take any action.
Main outcome variables
Pain Stress Nausea and vomiting The amount of opioid needed Hemodynamic indices Blood indicators indicate pain and stress

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190325043107N10**
Registration date: **2019-09-14, 1398/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-14, 1398/06/23**
Update count: **0**
Registration date
2019-09-14, 1398/06/23

Registrant information
Name
Mehdi Khanbabayi Gol
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 41 3334 7054
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khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-06, 1398/06/15
Expected recruitment end date
2020-09-05, 1399/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of acupuncture on ear pain, blood parameters, hemodynamic indices, stress, nausea and vomiting in surgical candidates

Public title
The effects of ear acupressure in surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study

Exclusion criteria:
Problems in the ear Infection in the ear

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researcher and the data analyzer are blind to the type of grouping and division into different groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2019-03-11, 1397/12/20

Ethics committee reference number
IR.TBZMED.REC.1397.1059

Health conditions studied

1

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Pain

Timepoint
4 times a day, every six hours and six hours after surgery

Method of measurement
Visual Analogue Scale

2

Description
Stress

Timepoint
Once a day before surgery

Method of measurement
Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive right thalamus point massage for 15 minutes by a specialist masseur who is highly skilled in performing massages. The variables of hemodynamic status, blood parameters, pain, stress and nausea and vomiting will be measured before and after the intervention. The researcher and the person analyzing the data are blind during the study.

Category
Prevention

2

Description
Control group: This group will not receive any intervention.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Hospital

Full name of responsible person

Mehdi Khanbabayi Gol

Street address
Azadi Ave, Shahid Madani Hospital

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2

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

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Ajouyban@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available