

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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)

Phone

+98 41 3334 7054

Email address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3535 3696

Email

mkhanbabayi@yahoo.com

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mehdi Khanbabayi Gol

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 21 3335 5921

Email

mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

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

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

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Person responsible for updating data

Contact

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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