

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of auriculotherapy on postoperative pain intensity after cesarean section

Protocol summary

Study aim

Determining the effect of ericulotherapy on pain intensity after cesarean section in women referred to Imam Ali Medical Center in Amol

Design

Clinical trial with control group and sham group, with parallel, double-blind, randomized groups, which were randomly selected from the random number table, samples and randomly placed in groups using the output numbers of SPSS software version 19 Will take.

Settings and conduct

The surgical ward of Imam Ali Hospital in Amol is the site of the project. The researcher, with the help of the ward nurse, identifies the women who are on the list of cesarean section and meets and interviews with patients undergoing cesarean section. This study is double-blind and both the patient and the outcome assessor are unaware of the placement of patients in the experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: previous history of cesarean section, gestational age 37-40 weeks, age 18-35 years, similar anesthesia protocol. Exclusion criteria: History of diabetes, hypertension, kidney, liver and cardiovascular diseases, neurological and psychiatric diseases, as well as the use of any special drugs, smoking, alcohol, history of vaginal delivery, history of treatment of ear disease during the last six months.

Intervention groups

In the intervention group, auricular therapy will be applied bilaterally on both ears symmetrically. In the sham group, auriculotherapy will be performed for the group receiving the unreal massage in places other than the locations of the intervention group.

Main outcome variables

in the patient is the Visual Adjustment Scale (VAS), to assess pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130822014436N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Amir Emami Zeydi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2021-01-29, 1399/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of auriculotherapy on postoperative pain intensity after cesarean section

Public title

The effect of uriculotherapy on pain after cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Previous history of cesarean section, Gestational age 37-40 weeks age 18-35 years Similar anesthesia protocol

Exclusion criteria:

History of diabetes High blood pressure Kidney, liver and cardiovascular diseases, neurological diseases Consumption of any medicine, cigarettes, alcohol Vaginal delivery history History of ear disease treatment during the last six months

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple random sampling, individuals are divided into intervention and control groups using a random number table if they have inclusion criteria and availability.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, so that both the patient and the person evaluating the outcomes using the VAS tool were unaware of the placement of patients in the experimental and control groups, so the subjects and colleagues asked about the division. They will not be aware of the classification of the subjects and the relevant measures.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Sari, Imam Square, Joybar Three Ways, beginning of Vali-e-Asr Highway, Mazandaran University of Medical Sciences

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2020-07-15, 1399/04/25

Ethics committee reference number

IR.MAZUMS..REC.1399.7708

Health conditions studied**1****Description of health condition studied**

Pain after cesarean section

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Visual Analogue Scale(VAS)

Timepoint

Pain intensity will be measured and recorded at times (15-30-60 minutes) and (3-6-12-24 hours) after the intervention.

Method of measurement

the patient is the Visual Adjustment Scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A group that will be applied to Shen Men, Points Zero, pelvic, pelvis, abdomen, endocrine, uterus bilaterally on both ears symmetrically, auricular therapy.

Category

Treatment - Surgery

2**Description**

Control group: In this group, auricular therapy will be

performed in places other than the intervention group without pressure.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital in Amol

Full name of responsible person

Zohre Hosseini

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Nor road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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