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

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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

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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

Street address
Nor road

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Amol

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Mazandaran

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46171 41497

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Majid Saeedi

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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
Mazandaran University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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