Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of auriculotherapy on shoulder pain after cesarean section in pregnant women referring to medical educational centers of Rafsanjan University of medical sciences

Protocol summary

Study aim

Determination the effect of auriculotherapy on shoulder pain after cesarean section in pregnant women referring to medical educational centers of Rafsanjan University of medical sciences

Design

Two arm parallel groups (45 person in each groups), three blinded clinical randomized trial

Settings and conduct

In this clinical trial, participants will be selected by convenience sampling method. Random allocation will be done by minimization method based on the number of delivery and history of cesarean section to the two groups of control and intervention. In the intervention group, the earrings (two hours before surgery for up to 24 hours after surgery), will be placed on the shoulder and muscle relaxation points on both ears. In the control group, in the same time period (two hours before surgery for up to 24 hours after surgery), earrings will be placed on the placebo points on both ears. Then, one hour after surgery, 6 and 24 hours after surgery, in both groups, shoulder pain will be assessed using a numerical pain rating scale.

Participants/Inclusion and exclusion criteria

Inform consent for participation in the study, age between 18 to 40 years, gestational age more than 36 weeks and healthy points on the ear to put the earrings are the inclusion criteria. Contraindication for spinal anesthesia, addiction, using tranquilizer drugs before the surgery, fracture or dislocation of shoulder, chronic pain of shoulder or neck, history of shoulder trauma, history of mental illness and history of any abdominal surgery other than cesarean section are exclusion criteria.

Intervention groups

Intervention group: earrings (two hours before surgery for up to 24 hours after surgery) will be placed on the shoulder and muscle relaxation points on both ears.

Control group: earrings (two hours before surgery for up to 24 hours after surgery) will be placed on the placebo points on both ears.

Main outcome variables

Shoulder pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N8**
Registration date: **2019-01-20, 1397/10/30**
Registration timing: **prospective**

Last update: **2019-01-20, 1397/10/30**
Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of auriculotherapy on shoulder pain after cesarean section in pregnant women referring to medical educational centers of Rafsanjan University of medical sciences

Public title

Investigating the effect of auriculotherapy on shoulder pain after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inform consent for participation in the study Age between 18 to 40 years Gestational age more than 36 weeks Healthy points on the ear to put the earrings

Exclusion criteria:

Contraindication for spinal anesthesia; Addiction; Using tranquilizer drugs before the surgery; Fracture or dislocation of shoulder; Chronic pain of shoulder or neck; History of shoulder trauma; History of mental illness; History of any abdominal surgery other than cesarean section.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as history of cesarean section and number of deliveries. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient will not know that he/she is in the intervention group or control. The earrings will be placed on the ears by someone other than the researcher and the researcher will not be aware of the intervention and control groups. The analyzer will not know the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.RUMS.REC.1397.166

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

082

ICD-10 code description

Single delivery by cesarean section

Primary outcomes

1

Description

Score of shoulder pain using numerical pain rating scale

Timepoint

1, 6 and 24 hour after cesarean section

Method of measurement

Numerical pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group, earrings (two hours before surgery for up to 24 hours after surgery), will be placed on the shoulder and muscle relaxation points on both ears.

Category
Prevention

2

Description
Control group: in this group, in the same time period (two hours before surgery for up to 24 hours after surgery), earrings will be placed on the placebo points on both ears.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abitaleb Hospital

Full name of responsible person
Ali Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Maryam Abedini

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable