

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of foot reflexology and Auriculotherapy on pain and anxiety in women following elective cesarean section

Protocol summary

2015-11-06, 1394/08/15

Summary

The aim of this study is Comparison of the effect of auriculotherapy (ear acupressure) and foot reflexology (reflexology massage) on pain and anxiety after cesarean section. The inclusion criteria include singleton pregnancy; Labor pains not start; The elective cesarean section planned before the onset of labor; No Medical condition in mother (cardiac, respiratory, hepatic or neurologic); using Spinal analgesia for caesarean section; No addiction to drugs, sedatives and alcohol in mother. Exclusion criteria include uncomfortable feel in ear acupressure or foot massage; complications during and after surgery such as prolonged duration of surgery, excessive bleeding and fetal death. This clinical trial will be done in Omolbanin Hospital in Mashhad. 132 pregnant women eligible for selection and after obtaining write consent randomly divide into three groups (auriculotherapy, foot reflexology and control). reflexology or auriculotherapy perform for 20 minutes ,at 2 - 3 hours after injection of anesthetic. one and two hours after the intervention the pain and anxiety ,by the McGill Pain Questionnaire and Spielberger questionnaire, evaluate. In the control group only at this time the pain and anxiety evaluate. In all three groups ,at the request of the patient's, routine analgesics used and its will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122920475N1**

Registration date: **2015-11-06, 1394/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Razieh Joghataei

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

90 percent Mashhad University of Medical Sciences , 10 percent Evidence-based research center

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of foot reflexology and Auriculotherapy on pain and anxiety in women following elective cesarean section

Public title

Comparison of the effect of ear acupressure and foot reflexology on pain and anxiety in women following elective cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria include singleton pregnancy; gestational age more than 37 weeks; Labor pains not start; The elective cesarean section planned before the onset of labor; using Spinal analgesia for caesarean section; No Medical condition in mother (cardiac, respiratory, hepatic or neurologic); normal body mass index ($18.5 < \text{BMI} < 30$) in first trimester of pregnancy; lack of injuries and wounds at the feet or ears; no history of migraine; no History of foot reflexology or Auriculotherapy; No addiction to drugs, sedatives and alcohol in mother. Exclusion criteria: uncomfortable feel in ear acupressure or foot massage; Lack of cooperation from the study; the cesarean incision is not transverse; complications during and after surgery such as excessive bleeding , adhesions, fetal death and prolonged duration of surgery(more than 1 hour).

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Avenue next to the cinema Hoveizeh- Mashhad
Medical Sciences- Department of Science and
Technology

City

Mashhad

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MUMS.REC.1394.261

Health conditions studied

1

Description of health condition studied

Cesarean pain and anxiety

ICD-10 code

o82

ICD-10 code description

single delivery by caesarean section

Primary outcomes

1

Description

pain

Timepoint

2-3Hours after anesthetic injection - 2 and 3 hours after
Intervention

Method of measurement

McGill pain questionnaire-Visual Analogue Scale

2

Description

Anxiety

Timepoint

3-2 hours after injection of anesthetic- One and two
hours after the intervention.

Method of measurement

Anxiety Inventory Spielberger

Secondary outcomes

1

Description

Nausea -Bloodshed

Timepoint

One and two hours after the intervention.

Method of measurement

Nausea visual analogue scale

2

Description

Bloodshed

Timepoint

One and two hours after the intervention.

Method of measurement

Weighing pads soaked in blood

Intervention groups

1

Description

foot reflexology prformed in the first intervention group.
Reflexology intervention performed once for 20 minutes
in both legs 2-3 hours after injecting anesthetic for spinal
anesthesia.

Category
Behavior

2

Description

In the control group does not take action

Category
N/A

3

Description

in the second intervention group Auriculotherapy performed once for 20 minutes in both ears.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin Hospital

Full name of responsible person

Fatemeh Mosavi

Street address

Bahjat 16, Bahjat street, Crossroads Zarina,Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad Univercity of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Department of Research and Technology, Mashhad University of Medical Science.behind of Hoveyzeh cinema,Danesgah stret,Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad Univercity of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mousavi Fatemeh sadat

Position

Midwifery students

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Golmakani Nahid

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Joghataei Razieh

Position

Biostatistics student

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty