Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

2015-11-06, 1394/08/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

90 prcent 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< 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
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Person responsible for updating data

Contact
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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