

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Study of the effect of Auriculotherapy on nausea and vomiting in women following elective cesarean section

Protocol summary

Study aim

evaluation of the effects of auriculotherapy on Nausea and vomiting in patients after cesarean section

Design

clinical trial with Two arm parallel group, single blind

Settings and conduct

This single-blind randomized clinical trial study was performed on 60 pregnant women who referred to Mashhad Omolbanin hospital for caesarean section . Participants were randomly assigned to two groups of control and intervention. In the intervention group, 30 min prior to spinal anesthesia, auriculotherapy (in shenmen, subcortex, kidney and abdominal points) was performed for 20-30 seconds by electrodermal stimulation and auricular seeds fixed on this points. In the control group, labels without seeds were attached to unrelated points (as a placebo). The incidence and severity of nausea and vomiting were assessed before the intervention, during the surgery, at recovery room and two hours after the surgery, using visual analog scale (VAS).

Participants/Inclusion and exclusion criteria

Inclusion criteria: No addiction to drugs, sedatives and alcohol in mother, lack of injuries and wounds at the ears, no History of Auriculotherapy, No taking antiemetic or emetic medications or herbal medications during past twenty-four hours and no history of hyperemesis gravidarum. Exclusion criteria: The patient's unwillingness to continue cooperation in research, complications during and after surgery such as excessive bleeding , adhesions, fetal death and prolonged duration of surgery(more than 1 hour), Failure of spinal anesthesia

Intervention groups

In the intervention group, 30 min prior to spinal anesthesia, auriculotherapy (in shenmen, subcortex, kidney and abdominal points) was performed for 20-30 seconds by electrodermal stimulation and auricular seeds fixed on this points. In the placebo group, labels

without seeds were attached to unrelated points.

Main outcome variables

بروز و شدت وقوع تهوع و استفراغ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039845N1**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Fatemeh sadat Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3622 2335

Email address

fmousavi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-09, 1395/02/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2017-09-11, 1396/06/20

Trial completion date
2017-09-11, 1396/06/20

Scientific title
Study of the effect of Auriculotherapy on nausea and vomiting in women following elective cesarean section

Public title
Effect of Auriculotherapy on nausea and vomiting in women following elective cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having an age range of 18 to 45 years; singleton pregnancy and gestational age more than 37 weeks; Labor pains not start, The elective cesarean section planned before the onset of labor, No Medical condition in mother (cardiac, respiratory, hepatic or neurologic); No addiction to drugs, sedatives and alcohol in mother, lack of injuries and wounds at the ears, no history of migraine and no History of Auriculotherapy, using Spinal analgesia for caesarean section, No taking antiemetic or emetic medications or herbal medications during past twenty-four hours and no history of hyperemesis gravidarum.
Exclusion criteria:
The patient's unwillingness to continue cooperation in research, complications during and after surgery such as excessive bleeding , adhesions, fetal death and prolonged duration of surgery(more than 1 hour) Failure of spinal anesthesia

Age
From **18 years** old to **38 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were assigned in each group according to block randomization. The size of the blocks was equal to 4.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient didn't know that she is in the intervention or control(sham) group. Both ears of all subjects of each group were attached with labels, while the labels did not differ in color and appearance. In the intervention group labels with seeds fixed on specific auricular acupuncture points but in control group labels without seeds were attached in sham points; and the subjects were not informed of the main and sham points.

Placebo

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

مشهد

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2016-01-02, 1394/10/12

Ethics committee reference number

IR.MUMS.REC.1394.586

Health conditions studied

1

Description of health condition studied

post cesarean nausea and vomiting

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

nausea and vomiting

Timepoint

during the surgery, at recovery room

Method of measurement

Nausea visual analogue scale

Secondary outcomes

1

Description

Anxiety

Timepoint

before the intervention and at recovery room

Method of measurement

Anxiety Inventory Spielberger

Intervention groups

1

Description

Intervention group: In the intervention group, 30 min prior to spinal anesthesia, auriculotherapy (in shenmen, subcortex, kidney and abdominal points) was performed for 20-30 seconds by electrodermal stimulation and auricular seeds fixed on this points.

Category

Treatment - Other

2

Description

Control group: In the control group (placebo), labels without seeds were attached to unrelated points

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin Hospital

Full name of responsible person

fatemeh sadat mousavi

Street address

Bahjat 16, Bahjat street, Crossroads Zarina,Mashhad

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Postal code

9137913199

Phone

+98 51 3859 1511

Email

golmakanin@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University 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

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

fatemeh sadat mousavi

Position

Midwifery students

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Ibn Sina street,Danesgah Street ,Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

nahid golmakani

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

fatemeh sadat mousavi

Position

Midwifery students

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only final analysis

When the data will become available and for how long

Time to print the article up to a year later

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no manipulation in the data

From where data/document is obtainable

Send a request by email, if not answered, phone call

What processes are involved for a request to access data/document

The requested time is about a week after the request is sent

Comments