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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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
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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
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Position

Associate professor

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Master

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Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Midwifery students

Latest degree
Master

Other areas of specialty/work
Midwifery

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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