Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the Effect of Auriculotherapy on Post-Cesarean Section Anxiety in women admitted to the postpartum ward

Protocol summary

Study aim

The aim of this study is to determine the effect of Auriculotherapy on anxiety after cesarean section

Design

The study is a clinical trial with a control and randomized group, without blinding, will be performed on 66 people. To generate a randomization list from the online randomization service Sealed Envelope Ltd. 2019 will be used.

Settings and conduct

This study will be performed in the postpartum ward of Al-Zahrah Educational, Research and Remedial Center in Rasht, affiliated to Guilan University of Medical Sciences. Intervention, Auriculotherapy will be performed on the intervention group. There is no intervention in the control group. Both groups will receive routine postpartum care. This study is not blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: signing informed written consent; having minimum literacy rate:'; trm pregnancy. Exclusion criteria: starting labor pains; sores, cysts or moles on the ea; smoking, alcohol and sedatives; emergency cesarean section.

Intervention groups

Intervention group: for this group, Auriculotherapy will be performed by placing a seed on one part of the left ear (Shen men) and 5 seed on the right ear (points: Master shoulder, Liver, Anxiety, sub cortex and relaxation point). In the first two days after cesarean section, the specimens should press their ears twice a day for 2 minutes each time, and from the third to the tenth day, press the seeds for one minute every hour. Questionnaires will be completed by the samples ten days after the intervention. Control group: in this group, only routine postpartum care will be performed.

Main outcome variables

State and Trait Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210607051505N1**
Registration date: **2021-06-23, 1400/04/02**
Registration timing: **prospective**

Last update: **2021-06-23, 1400/04/02**
Update count: **0**

Registration date

2021-06-23, 1400/04/02

Registrant information

Name

maryam niknami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

niknami@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2021-11-10, 1400/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effect of Auriculotherapy on Post-Cesarean Section Anxiety in women admitted to the postpartum ward

Public title
Evaluation the Effect of Auriculotherapy on Post-Cesarean Section Anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signing informed written consent Having minimum literacy rate Term and singleton pregnancy Having healthy neonate
Exclusion criteria:
Speech, hearing or mental problems that prevent communication with the researcher Medical and obstetric disorders Migraines Starting labor pain History of Auriculotherapy Sores, cysts or moles on the ears Smoking, hookah, alcohol and sedatives Intense emotional excitement of the mother in the last 6 months, including: separation from her husband, loss of a family member, accidents or unfortunate events for herself or a loved one Emergency caesarean section People who have had unsuccessful spinal anesthesia followed by general anesthesia
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The type of randomization is blocking and will be divided into two groups of Auriculotherapy and control using the block randomization method with the size of 4 and 6 blocks. The method used to generate the random allocation sequence is from the online randomization service Sealed Envelope Ltd. 2019 will be used (https://www.sealedenvelope.com/simple-randomiser/v1/lists) The method of concealing the allocation is to use sealed envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
Daneshjoo St, Rasht - Shahid Beheshti Highway, Rasht Town
City
Rasht
Province
Guilan
Postal code
39841-41469
Approval date
2021-06-01, 1400/03/11
Ethics committee reference number
IR.GUMS.REC.1400.109

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.8
ICD-10 code description
Other specified anxiety disorders

Primary outcomes

1

Description
State and trait anxiety scores in the Spielberg er questionnaire
Timepoint
Before the intervention, 2 and 10 days after the intervention
Method of measurement
The method of measuring the anxiety outcome variable is the Spielberg er overt and covert anxiety questionnaire. This tool contains 40 items, 20 of which are related to overt anxiety and 20 items are related to latent anxiety

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 2 times Auriculotherapy on the first day and 2 times an intervention on the second day after cesarean section / Vacaria herbal seeds will be pasted in

6 points related to anxiety / Continuation of Auriculotherapy every hour for one minute to ten days after cesarean section

Category

Treatment - Other

2

Description

Control group: no intervention / Routine postpartum care is provided

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational,Research and, Remedial Center

Full name of responsible person

Maryam Niknamy

Street address

Namjoo St, Rasht Town

City

Rasht

Province

Guilan

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39841-41469

Phone

+98 13 3355 5056

Email

niknami@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Guilan University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Daneshjoo St, Rasht - Shahid Beheshti Highway, Rasht Town

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Email

naghi@gums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Somayeh Sharifi Pirjel

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Daneshjoo St., Rasht - Shahid Beheshti Highway, Rasht Town

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som.sharifi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Niknami Maryam

Position

Faculty Member (Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Somayeh Sharifi Pirjel
Position
Master student of midwifery
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available