

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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; term pregnancy. Exclusion criteria: starting labor pains; sores, cysts or moles on the ear; 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 nikhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3355 5056

##### Email address

nikhani@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

**Postal code**

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

**City**

Rasht

**Province**

Guilan

**Postal code**

39841-41469

**Phone**

+98 13 3355 5056

**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

**City**

Rasht

**Province**

Guilan

**Postal code**

39841-41469

**Phone**

+98 13 3355 5056

**Email**

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

**Street address**

Daneshjoo St., Shahid Beheshti Highway, Rasht Town

**City**

Rasht

**Province**  
Guilan  
**Postal code**  
39841-41469  
**Phone**  
+98 13 3355 5056  
**Email**  
niknami@gums.ac.ir

39841-41469  
**Phone**  
+98 13 3355 5056  
**Email**  
som.sharifi@gmail.com

## 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**  
Midwifery  
**Street address**  
Shahid Beheshti Blvd., Rasht town  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**

## 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