

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Investigating the effect of ear acupressure on postpartum blues: A randomized sham controlled trial

Protocol summary

Study aim

Comparison of postpartum blues intensity in the study groups after intervention

Design

Clinical trial with sham control group, in parallel groups, triple blind, randomized, phase 3 on 74 patients. Randomization will be done using online random generator software.

Settings and conduct

This study is a randomized Sham controlled clinical trial, which will be performed on primiparous mothers at Kowsar Hospital in Qazvin. First external earlobes will be cleaned with 75% alcohol and then special non-latex adhesives with vaccaria seeds will be adhered with on 5 points of the left ear, including the endocrine master, my sand, Zero, Gonadotroin, Master cerbal and 2 points of right side includes the thalamic and antidepressant points. The number of interventions is 2 times with an interval of 5 days. Participants are taught to keep the seeds in their ears for five days, during this time, they must press each point three times a day for twenty seconds. In the control group, a similar visit is made and non-latex adhesives without vaccaria seeds will be placed on their ear. Therefore, the participant, clinical caregiver, and outcome assessor and data analyzer will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

In this study, primiparous women with term pregnancy and a singleton baby with a healthy earlobe will be invited to study.

Intervention groups

1- Intervention group of auriculotherapy 2- Sham control group

Main outcome variables

Intensity of postpartum blues

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038789N2**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **prospective**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name

Zainab Alimoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6003

Email address

z.alimoradi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ear acupressure on postpartum blues: A randomized sham controlled trial

Public title

Investigating the effect of ear acupressure on postpartum blues

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Being primiparous Born a full term, singleton baby Having a healthy earlobe with no lesions, sores and pain in the earlobe Being Iranian Being literate at least with ability in reading and writing Availability during the study period (residence in Qazvin city)

Exclusion criteria:

Complications in pregnancy and postpartum (e.g. preterm delivery, preeclampsia, gestational diabetes, infant in need of special care, etc.) History of chronic mental and physical illness (self-report and review of the individual's file) Drug abuse in the individual or his spouse History of acupressure in the last three months History of stressful events in the last three months (such as the loss of loved ones)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done using balanced block randomization methods with each block size of 4. The allocation sequence will be generated using online software. After preparing the allocation sequence, the sequence will be written down on paper in order and placed inside the closed sealed envelopes. Envelopes are numbered sequentially. Questionnaires are coded in the same way. Accordingly, each person will be assigned to one of the intervention or control groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the control group will receive the same intervention as the main group (sham control). Therefore, participants will not know what group they are in. Since the clinical caregiver and the outcome assessor and data analyst are not aware of this, blindness of the second and third levels will also be implemented.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

34199-15315

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.QUMS.REC.1399.050

Health conditions studied

1

Description of health condition studied

Postpartum blues

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of postpartum blues

Timepoint

pre-intervention, 5 , 10 , 15 days after intervention

Method of measurement

Maternity Blues Questionnaire

Secondary outcomes

1

Description

Intensity of postpartum tiredness

Timepoint

pre- intervention, 5, 10, 15 , 21 days after intervention

Method of measurement

Iowa tiredness scale

2

Description

Maternal attachment

Timepoint

pre- intervention, 5, 10, 15 , 21 days after intervention

Method of measurement

Muller Maternal Attachment Index

3

Description

Intensity of postpartum depression

Timepoint

21 days after intervention

Method of measurement

Edinburgh Postnatal Depression scale

Intervention groups

1

Description

Intervention group: Auriculotherapy

Category

Prevention

2

Description

Control group: Sham control

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital, Qazvin

Full name of responsible person

Zainab Alimoradi

Street address

Vali-Asar Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr EmamJomeh

Street address

Shahid Bahonar Boulevard- Qazvin University of
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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data related to the study will be published as an anonymous and unrecognizable file at the same time as the publication of the results as an appendix.

When the data will become available and for how long

After the publication of the article, the results of the data design will be available

To whom data/document is available

All people can access the data by referring to the appendix of published article

Under which criteria data/document could be used

All people with no limitation can access data

From where data/document is obtainable

Appendix of published article

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

Email to corresponding author

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

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