Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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Vali-Asar Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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Dr EmamJomeh
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Shahid Bahonar Boulevard- Qazvin University of Medical Sciences- School of Nursing & Midwifery
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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
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Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

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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