

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Auriculotherapy on Lactation of Women who underwent Caesarean sections

Protocol summary

Study aim

To determine the effect of Ear Acupuncture on lactation of women who underwent caesarean sections

Design

One-blind sham controlled clinical trial with a parallel group design of 86 patients, randomized by Excel software into two groups

Settings and conduct

Sampling will perform in 2 selected Hospitals in Rafsanjan. Participants will meet criteria for Insufficient breastfeeding. They will then randomly divided into two groups of 43 people. Infant weight, breast volume and maternal serum prolactin level will measured before and then after the research. The intervention group receives acupressure of Ear by Vakaria seed on the dominant auricular points that include Prolactin, Endocrine, Small intestine1, Shen men and Liver for three times a day and one minute each time during ten days and recessive ear points that include Mammary gland, Kidney and Sympathetic autonomic points receives acupressure with same method. Sham control group will receives label without Vakaria seeds in same points with out any stimulation, so the participant will be blind to the type of treatment. On the tenth day of the intervention Sufficient breastfeeding, Uterine recovery Will be checked.

Participants/Inclusion and exclusion criteria

Age between 18 and 38 years, Gestational age between 37 and 42 weeks, Single fetus, Meet objective and perceived criteria for inadequate breastfeeding in the morning of the first day after cesarean section, Normal BMI, No known chronic systemic diseases, lack of breast problems, no taking any drugs interfering milk production and any methods for increasing lactation, Lack of adverse outcomes for infants and mothers

Intervention groups

Intervention group receives acupressure of Ear by Vakaria seed , Sham control group will receives label without Vakaria seeds

Main outcome variables

Infant weight, breast volume, serum prolactin level, Sufficient breastfeeding, Uterine recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201020049086N1**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Fatemeh Khorasanian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-24, 1400/04/03

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Auriculotherapy on Lactation of Women who underwent Caesarean sections

Public title

The effect of Ear acupressure on lactation of women who underwent caesarean sections

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age of 37-42 weeks Has objective and perceived criteria for breastfeeding inadequacy according to the checklist The mother has a normal body mass index (19.8-26 kg / m²) Having the ability to write and read Live single fetus Baby weighing between 2.5 and 4 kg The infant has no low Apgar score, jaundice and congenital malformations The infants should have sucking and rooting reflexes and complete neural development The mother should not have chorioamnionitis, preeclampsia and diabetes in the current pregnancy Mothers should not be addicted to drugs, psychotropic drugs or alcohol Mothers should not have Untreated Active Tuberculosis or Immunodeficiency Virus No known medical conditions such as Chronic systemic diseases and advanced cancer The woman should not have breast problems such as abscesses, nipple dislocations, and low or non-glandular tissue of the breast Mothers should not have ear piercings in the areas intended for acupressure

Exclusion criteria:

Lack of desire of mothers to continue to participate in research Failure to perform acupressure as taught in three consecutive times The mother stops breastfeeding for any reason Signs of infection, bleeding, shock and convulsions after delivery Infant hospitalization in neonatal intensive care unit Use other methods to increase breastfeeding Any physical and mental illness that disrupts breastfeeding, such as liver disease, cancer, mammalian problems and Postpartum depression

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method, using an Excel spreadsheet. In the Excel spreadsheet the leftmost

column shows the total number of participants, which in the current study will be 86. First we arrange the random numbers then in ascending order. The next column indicates the group to which participants belong, with the top half in Group A and the bottom half in Group B. For the next column is filled using the "Rand" function; this function generates random numbers for all individuals, so the individuals will be randomly ordered within each of the two groups. At the end they enter the study according to the order of referral and allocate a code to them. Random unit: individual Randomization Tool: Software

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, sham control group will be matched with ear acupressure group in terms of all confounding variables but the type of label used in sham control group will be without Vakaria seeds and the mother will not stimulate the points. In this way, the participant and data Analyzer will not know how the groups are assigned. For this purpose, a complete explanation of the interventions will be given to the participant before random allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Ethics Committee of the Faculty of Pharmacy and Nursing Midwifery of Shahid Beheshti U

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

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Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.012

Health conditions studied**1****Description of health condition studied**

Breastfeeding
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Maternal serum Prolactin

Timepoint

At the beginning of the study (before the intervention)
and Tenth day after cesarean delivery (end of the study)

Method of measurement

Prolactin Laboratory Kit

2

Description

Baby weight gain

Timepoint

At the beginning of the study (before the intervention)
and Tenth day after cesarean delivery (end of the study)

Method of measurement

Digital scales for children

3

Description

Breast volume

Timepoint

At the beginning of the study (before the intervention)
and Tenth day after cesarean delivery (end of the
intervention)

Method of measurement

Height and radius of the breast will be measured by
Caliper and placed in the volume formula

4

Description

Sufficient breastfeeding

Timepoint

Tenth day after cesarean delivery(end of the
intervention)

Method of measurement

Sufficient breastfeeding questionnaire

5

Description

Uterine recovery

Timepoint

Tenth day after cesarean delivery(end of the
intervention)

Method of measurement

Touch Uterine fundus from the abdomen

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receives acupressure of Ear by Vakaria seed on the dominant auricular points that include Prolactin, Endocrine, Small intestine1, Shen men and Liver for three times a day and one minute each time during ten days and recessive ear points that include Mammary gland, Kidney and Sympathetic autonomic points receives acupressure with same method in dominant ear. The above points will be identified by the researcher and using the Pointer Excel 2 device.

Category

Treatment - Devices

2

Description

The sham control group receives the intervention by application of label without Vakaria seeds and any stimulation in the same areas of the acupressure intervention group. The above points will be identified by the researcher and using the Pointer Excel 2 device.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs Maternity

Full name of responsible person

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Khorasanian

Position

Master Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Shahid Beheshti 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Simbar

Position

Professor

Latest degree

Ph.D.

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

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Protocol and data files

When the data will become available and for how long

After publishing the article

To whom data/document is available

For Journal reviewers and the readers of the article if they need

Under which criteria data/document could be used

If they asked

From where data/document is obtainable

Midwifery and Reproductive Health Research Center
Shahid Beheshti University of Medical Sciences

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

email to researchers

Comments