

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

The effect of two methods of uriculotherapy and reflexology on the severity of labor pain and the duration of the active stage of labor

Protocol summary

Study aim

Investigating the effect of two methods of auriculotherapy and reflexology on the intensity of labor pain and the duration of the active stage

Design

Clinical trial with intervention and control group, with parallel groups, single-blind, randomized, phase 3 on 96 patients. For randomization, simple randomization is done using Random Allocation software..

Settings and conduct

This study will be conducted in Bahar Shahrood Hospital. Patients are randomly divided into three groups using Random Allocation software. The most important outcome evaluated in this study is the intensity of labor pain and the duration of the active phase of labor. In order to obtain data on this outcome, the intensity of labor pain will be measured first at 4 cm dilatation, then at 6 and 8 cm dilatation. The statistical analyst does not know how the groups are coded and the blinding of one strain is done..

Participants/Inclusion and exclusion criteria

Low-risk pregnancy (no placental placenta, no polyhydramnios, reduced fetal movements and IUGR) Gestation age 37-40 weeks 3. Cephalic presentation 4. Singleton pregnancy 5. First pregnancy 6. 4 cm dilation and uterine contractions for 30 seconds and 2-3 contractions in 10 minutes 7. Age between 18-35 years 8. $19/9 < \text{body mass index} < 25/9$ 9. Having minimum literacy 10. Having at least one healthy ear 11. Having at least one healthy leg (absence of cuts, burns, fungal infections, warts, warts and any kind of numbness in the leg) 12. Has a safe water bag 13. No history of infertility 14. Absence of cesarean indications 15. Declaration of informed consent

Intervention groups

First intervention group: Auriculotherapy .The second intervention group: Reflexology metho and Control group: routine care method is used.In each of the methods, 20 minutes of massage will be done twice.

Main outcome variables

Pain intensity, pain duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220910055928N1**

Registration date: **2022-10-31, 1401/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-31, 1401/08/09**

Update count: **0**

Registration date

2022-10-31, 1401/08/09

Registrant information

Name

ZEYNAB Ameri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3251 3250

Email address

zeynabameri2014@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of two methods of uriculotherapy and reflexology on the severity of labor pain and the duration of the active stage of labor

Public title

The effect of two methods of uriculotherapy and reflexology on the severity of labor pain and the duration of the active stage of labor

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

obtaining informed consent. Low-risk pregnancy (not having a placenta, no polyhydramnios, reduced fetal movements, as well as IUGR Gestation age 37-40 weeks Singleton pregnancy Cephalic presentation 4 cm dilation and uterine contractions for 30 seconds and 2-3 contractions in 10 minutes Age between 18-35 years Having at least reading and writing literacy Having at least one healthy ear Having at least one healthy foot (absence of cuts, burns, fungal infections, warts, warts, and any kind of numbness in the foot) Has a safe water bag

Exclusion criteria:

Receiving painkillers within 3 hours before the start and during the study Drug addiction Using oxytocin to induce and accelerate childbirth Emergency caesarean section for any reason before the completion of the first stage of labor

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using Random Allocation software and simple randomization method, and people are examined in one of three groups. Then prepare 96 numbered envelopes that contain the treatment method code and the informed consent form, and one of the envelopes will be assigned in the order of number when people enter.

Blinding (investigator's opinion)

Single blinded

Blinding description

To prevent the study analyst from knowing, each group will be assigned a code that only the researcher will know about their interpretation, and coded information will be delivered to the statistical consultant for analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences, Heftam Tir Square, Tehran Street

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۳

Approval date

2022-07-30, 1401/05/08

Ethics committee reference number

IR.SHMU.REC.1401.128

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

The effect of reflexology and auriculotherapy on the severity of labor pain

ICD-10 code

061

ICD-10 code description

Failed induction of labour

Primary outcomes**1****Description**

severity of labor pain

Timepoint

Time intervals of pain intensity measurement by visual pain scale will be done first at 4 cm dilatation and then at 6 and 8 cm dilatation.

Method of measurement

The way to measure the outcome variable will be a horizontal ruler (visual scale of pain).

2**Description**

the duration of the active phase of labor

Timepoint

Time intervals of pain intensity measurement by visual pain scale will be done first at 4 cm dilatation and then at 6 and 8 cm dilatation.

Method of measurement

The way to measure the outcome variable will be a horizontal ruler (visual scale of pain)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In the auriculotherapy group, after disinfecting the ear in the lobe of the ear, on the points located in the figure (1-1, 1-2, and 1-3), including the parts of the uterus, pituitary gland, pelvis, adrenal gland, endocrine gland and the point of Shan Man, spleen point and the thoracos point, pressure is applied once at 4 cm dilatation and again at 6 to 8 cm dilatation for 20 minutes each. Then the researcher will observe the mother until delivery and after that.

Category

Treatment - Other

2

Description

The second intervention group: gentle massage on the entire sole of the foot, and then pressure will be applied on the specified and relevant areas. These areas will include the pituitary gland, right in the center of the big toe of both feet, the solar plexus approximately four toes wide below the base of the toes of both feet and in the center. The genital area is located below the ankles of both legs and on both sides. Reflexology will be performed for 20 minutes on each leg for a total of 40 minutes starting with 4 cm dilation and entering the active phase of labor by the researcher, and again at 6 and 8 cm dilation, then the researcher until the time of delivery and after that. will monitor the mother.

Category

Treatment - Other

3

Description

Control group: In the control group Zao will receive only routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital

Full name of responsible person

Zainab Ameri

Street address

22 Bahman Street, in front of the Children's Park, Bahar Hospital

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zeynabAmeri2014@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

zeynab Ameri

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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

Shahrood 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

Shahrood University of Medical Sciences

Full name of responsible person
zeynab Ameri
Position
midwife
Latest degree
Master
Other areas of specialty/work
Midwifery
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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

Yes - There is a plan to make this available

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

Main implications of the study.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

It will be used to cite the source in the articles and any other type of analysis will be done in consultation with the first author of the article

From where data/document is obtainable

To receive the desired documents or data, please email Ms. Zainab Ameri, Master of Midwifery Counseling, working at Bahar Hospital, at ameri.z@shmu.ac.ir or call 00982332395054.

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

To receive documents or other items after applying, they will receive a clear answer within two weeks.

Comments