# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of two methods of uriculotherapy and reflexology on the severity of labor pain and the durationof 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 < 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: Refluxology 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 durationof the active stage of labor

**Public title**
The effect of two methods of uriculotherapy and reflexology on the severity of labor pain and the durationof 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

**City**

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**Province**

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**Postal code**

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**Email**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

zeynab Ameri

**Street address**

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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**

Shahroud 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**

Shahroud 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 scientific inquiries

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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**