Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Auriculotherapy on labor pain and Anxiety in nulliparous women

Protocol summary

Study aim
Determining the effect of auriculotherapy on the severity of pain and anxiety during vaginal delivery

Design
a clinical trial with a randomized parallel blind control group on 80 nulliparous pregnant women. This is done by the random block method

Settings and conduct
The study was performed at Shohada Hospital in Qom. In the intervention group, labels containing Vakaria seeds were affixed at 5 points in both ears, first in the dilation of 4-5 cm, then in dilatation of 7-8 cm, each point for one minute (in total 20 minutes) is pressed by the researcher. The control group affixes simple labels that are similar in color and appearance to irrelevant points and the subjects are blind and will not know the type of treatment. Severe pain with visual aids Pain and anxiety with The obvious Spielberger questionnaire is measured in the stages immediately after the intervention, dilation 7-8 cm, and the beginning of the second stage of labor.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18-40 years, first pregnancy, gestational age 37-32 W/presentation of cephalic, BMI 26- 8/19. No wound or lesion in the corner, Cervical dilation 3-4 cm، No previous treatment with auriculotherapy, No midwife.Exclusion criteria: Lack of cooperation to continue the study, receiving epidural or spinal anesthesia, drug addiction, use of oxytocin, obstetric problems, the emergency cesarean section.

Intervention groups
In the intervention group, the researcher pasted the labels containing Vakaria seeds in 5 points of the sand, uterine, external genitalia, cerebral and autonomic in both ears, first in dilation 4-5 Cm and then in dilation 7-8 cm, each point is pressed by the researcher for one minute in the interval between uterine contractions (20 minutes in total). In the control group, simple labels that are similar in color and appearance are pasted.

Main outcome variables
Pain،Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171106037279N3**
Registration date: **2021-08-28, 1400/06/06**
Registration timing: **prospective**

Last update: **2021-08-28, 1400/06/06**
Update count: **0**

Registration date
2021-08-28, 1400/06/06

Registrant information

Name
farzaneh nasiri

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-06, 1400/07/14

Expected recruitment end date
2022-05-25, 1401/03/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Auriculotherapy on labor pain and Anxiety in nulliparous women

Public title
The effect of Auriculotherapy on labor pain and Anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The mother should be 18-40 years old and the first pregnancy, the gestational age should be 37-42 weeks (term), the cephalic presentation and the pregnancy should be single, the mother should be at least literate, the mother's body mass index before pregnancy or three months The first pregnancy is 19.8-26, there is a wound or lesion in the ears, the uterine contractions spontaneously and the cervical dilatation is 3-4 cm, the mother hasn't an acute and chronic psychological problem, the mother is currently taking Related drugs. Do not be nervous, do not use cigarettes or drugs, the mother is not capable of any disease or complications of pregnancy, is not destroyed in this pregnancy, has not been treated with auricular therapy, Does not have a midwife with you.

Exclusion criteria:
Lack of cooperation to continue the study, receiving epidural or spinal anesthesia, drug addiction, use of oxytocin to induce and accelerate labor, obstetric problems during labor, emergency cesarean section before completing the study, vital signs of the mother are not in the normal range

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation Using the random block method (patients are randomly divided into 20 blocks of 4), research units are divided into two groups of auricular therapy, placebo. Individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we have six quadruple blocks consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. The selection of each block is random and will be done by throwing the dice twenty times (until the assignment of patients to treatment groups is completed). Assignment of treatment (auricular therapy and placebo) to the intervention and control groups will also be done randomly.

Blinding (investigator's opinion)
Single blinded

Blinding description
Subjects did not know whether they had received actual treatment or a placebo

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
Qom / Kahak section, Imam Hossain street, Reza Ahmadi house

City
Qom

Province
Ghoum

Postal code
1234567890

Approval date
2020-12-15, 1399/09/25

Ethics committee reference number
IR.MUQ.REC.1399.247

Health conditions studied

1

Description of health condition studied
Pain and anxiety of nulliparous women

ICD-10 code

ICD-10 code description
باردار

Primary outcomes

1

Description
Pain and anxiety of nulliparous women

Timepoint
Before, during and after delivery

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: If the vital signs are normal, the researcher affixed the labels containing Vakaria seeds after disinfecting the ear with 70% alcohol in 5 points of sand, uterine, external genitalia, cerebral and autonomic in both ears, first in dilation of 4-5 cm and then In dilatation 7-8 cm, and each point is pressed by the researcher for one minute in the interval between uterine contractions (a total of 20 minutes)
Category
Other

2

Description
Control group: Simple tags (without Vacaria seeds) that are similar in color and appearance are pasted in 5 points: sand, uterine, external genitalia, and cerebral and autonomic in both ears.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Farzaneh Nasiri
Street address
Qom / Kahak section / Imam Hossein street / Reza Ahmadi house
City
Qom
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123456789
Phone
+98 25 3423 1395
Email
farzanehnasiri100@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Farzaneh nasiri
Street address
Qom / Kahak section / Imam Hossein street / Reza Ahmadi house
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Email
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
فرزانه نصیری
Position
student
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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student
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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
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
Demographic information and information obtained from the questionnaire
When the data will become available and for how long
After publishing the article in the journal
To whom data/document is available
Researchers, Department of Medical Sciences
Under which criteria data/document could be used
Use to treat other patients
From where data/document is obtainable
Email farzanehnasiri100@ gmail.com farzaneh nasiri
What processes are involved for a request to access data/document
Send message via email
Comments