Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Auriculotherapy effect on pain intensity, duration of active phase of labor and episiotomy rate in nulliparous women

Protocol summary

Summary

this study is to determine the effect auriculotherapy on pain intensity, duration of active phase of labor and rate episiotomy in nulliparous women. In this randomized controlled clinical trial, 80 nulliparous pregnant women were assigned to two groups. Auriculotherapy was used for the case group, the control group received no intervention. Primiparous women in the study population Sina and Imam Khomeini Hospital, city of Ahvaz. Admission criteria samples gestational age 37-40 weeks, cephalic presentation, singleton pregnancy, 4 cm dilation and uterine contractions in 10 minutes, 30 seconds and 3-2, age between 18-35 years, have someone clean water (Intact) and exclusion criteria of the study: taking pain medications during the 3 hours before and during the study, history of infertility, use of oxytocin for induction or augmentation of labor are. Intervention techniques auriculotherapy by the investigator when the mother is in pain, and the pain is not the first time when the Bishop 4 and then Dilatation 6 and 8 cm, then sterilizing the ear,is on the auricle on points desired. the primary outcomes pain intensity and duration of the active phase of labor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101919591N1**
Registration date: **2014-11-27, 1393/09/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-27, 1393/09/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

AJUMS

Expected recruitment start date

2014-10-30, 1393/08/08

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Auriculotherapy effect on pain intensity, duration of active phase of labor and episiotomy rate in nulliparous women

Public title

Auriculotherapy effect on pain intensity, duration of active phase of labor and episiotomy rate

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: low risk pregnancy ; gestational age of 37-40 weeks ; cephalic presentation ; singleton pregnancy ; 4 cm dilation and uterine contractions in 10 minutes, 30 seconds and 3-2 ; age among 18-35 year ;

26.4 >BMI >19.8 ; have at least read and write ; having at least one healthy ear ; have someone clean water (Intact) Exclusion criteria of the study were to: receive pain medications during the 3 hours before and during the study ; drug addiction ; Athlete ; history of infertility ; the use of oxytocin for induction or augmentation of labor

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jondishapour University of Medical Sciences

Street address
Ahvaz, Golestan Highway, University of Medical Sciences Jondishapour Ahvaz

City
Ahvaz

Postal code
61357-15794

Approval date
2014-09-28, 1393/07/06

Ethics committee reference number
ajums.REC.1393.190

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
O80.0

ICD-10 code description
spontaneous vertex delivery

2

Description of health condition studied
delivery

ICD-10 code
080.9

ICD-10 code description
spontaneous delivery,Single unspecified

Primary outcomes

1

Description
Severity of labor pain

Timepoint
Beginning of the active phase of dilatation of 6 cm and 8 cm

Method of measurement
visual analogue scale

2

Description
The duration of the active phase

Timepoint
During the first stage of labor

Method of measurement
Time recorded by the investigator

3

Description
episiotomy rate

Timepoint
In time of delivery

Method of measurement
recorded by the investigator

Secondary outcomes

1

Description
Durationof the second stage of labor

Timepoint
During the second stage of labor

Method of measurement
During the second stage of labor

2

Description
Duration of the third stage of labor

Timepoint
During the third stage of labor

Method of measurement
During the third stage of labor

Intervention groups

1

Description
In the intervention group: Auriculotherapy / three times / in the active phase of labor / in Dilatation 4 cm and 6 cm and 8 cm
Category
Treatment - Other

2

Description
In the control group :does not intervention / monitoring
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Hoda Rastegarzade
Street address
Iran, Ahvaz, Kut Abdullah Road, Not far from the Alley station, Sina Hospital
City
Ahvaz

2

Recruitment center
Name of recruitment center
Emam khomeini Hospital
Full name of responsible person
Hoda Rastegarzade
Street address
Iran, Ahvaz, street twenty-four meters, Imam Khomeini Hospital
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences
Full name of responsible person
Dr. Seid Ahmad Hosseini
Street address
Ahvaz Jundishapur University of Medical Sciences, opposite the central building, Vice Chancellor for Research, Ahvaz University of Medical Sciences
City
Ahvaz

Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
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Hoda Rastegar Zade
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Master of Midwifery
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty