

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Hoda Rastegar Zade

Name of organization / entity

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Country

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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

O80.9

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

Duration of 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

Full name of responsible person

Hoda Rastegar Zade

Position

Master of Midwifery

Other areas of specialty/work

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University of Medical Sciences, School of nursing and

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