Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison auriculotherapy and K3 point acupressure on pain intensity and duration of labor in nulliparous women.

Protocol summary

Study aim
Comparison ofauriculotherapy and K3 point acupressure on pain intensity and duration of labor in nulliparous women in Zarand hospital in 2021.

Design
A clinical trial with a control group, with parallel, randomized groups, on 90 patients. Simple randomization and sampling available. R software is used for randomization.

Settings and conduct
Primiparous women will be referred to Zarand Hospital in the active phase in 37-40 weeks. They will be randomly assigned to intervention and control groups.In this study, there is no blinding due to the knowledge of the researcher and participants about the applicable methods.

Participants/Inclusion and exclusion criteria
Low risk pregnancy, age 37-40 weeks of pregnancy, cephalic presentation, singleton pregnancy, dilatation 4 cm, age between 18-35 years, having at least one healthy ear.

Intervention groups
this study, we will have 2 intervention groups and a control group. In the intervention group, auriculotherapy was performed for the first time in dilatation 4 and then in dilatation 6 and 8 cm. Zero, prostaglandin point and relaxation point will be stimulated for the intervention group with a hand probe for one minute and a side of Vakaria plant type. In the acupressure intervention group, in the K3 acupressure intervention group, after finding this point, which is located on the inner surface of the foot and between the Achilles tendon and the inner ankle, first in dilatation 4 and then in dilatation of 6 and 8 cm for 30 seconds. Press and rest for 30 seconds for 20 minutes at each stage. The control group receives routine interventions. Pain intensity is measured before the intervention and immediately after the intervention using a visual instrument for pain intensity, which is graded between zero and 10.

Main outcome variables
Reduction of labor pain and duration of labor

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170624034722N1**
Registration date: **2021-05-19, 1400/02/29**
Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**
Update count: **0**
Registration date
2021-05-19, 1400/02/29

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5177
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f_mirzaee@kmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-22, 1400/03/01
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The Comparison auriculotherapy and K3 point acupressure on pain intensity and duration of labor in nulliparous women.

Public title
Comparison of auriculotherapy and K3 point acupressure on pain intensity and duration of labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Low risk pregnancy Gestational age 37-40 Cephalic presentation Single pregnancy Entering the active phase of childbirth Have at least one healthy ear Being between 35-18 years old

Exclusion criteria:
Receiving analgesic drug within 3 hours before the start of the study. Use of oxytocin to induce and accelerate labor. Drug addiction. Being an athlete. History of infertility.

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method is used, for this purpose, blocks of 6 are used and inside each block of 6, two people are randomly assigned to group A, two to group B and two to group C is allocated. 15 blocks of 6 are used for this study and the software used to allocate blocks is R software.

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
Ethics committee of KermanUniversity of Medical Sciences

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2021-02-22, 1399/12/04

Ethics committee reference number
IR.KMU.REC.1399.650

Health conditions studied

1

Description of health condition studied
labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Reduce pain intensity

Timepoint
Prior to intervention, in cervical dilatation 4, 6 and 8 cm

Method of measurement
Visual Analogue Scale

2

Description
Reduce the duration of labor

Timepoint
Time interval from dilatation of cervix 4 to 10 cm

Method of measurement
In terms of hours, the time between dilatation is 4 cm to 10 cm of the cervix.

Secondary outcomes

empty

Intervention groups

1

Description
In the auriculotherapy intervention group, was performed for the first time in dilatation 4 and then in dilatation 6 and 8 cm, after disinfection and massage of the ear, on the left ear Zero, prostaglandin point and relaxation point will be stimulated for the intervention group with a manual probe for one minute and a side of Vacaria plant type.

Category

Treatment - Other

2

Description
In the K3 acupressure intervention group, after finding this point, which is located on the inner surface of the foot and between the Achilles tendon and the inner ankle, first in dilatation 4 and then in dilatation of 6 and 8 cm for 30 seconds. Press and rest for 30 seconds for 20 minutes at each stage.

Category
Treatment - Other

3

Description
Control group: The control group receives routine interventions

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Zarand Hospital

Full name of responsible person
Firoozeh Mirzaee

Street address
Jomhoori Bld. Zarand hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Abas Pardakhtie

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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
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Firoozeh Mirzaee

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Position
Assistant prifessor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data can be shared after identifying individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Data will be provided to all applicants.
Under which criteria data/document could be used
Any kind of analysis on the data is allowed.
From where data/document is obtainable
Via the following email that belongs to Dr. Firoozeh Mirzaee: f_mirzaee@kmu.ac.ir
What processes are involved for a request to access data/document
By correspondence and e-mail with Dr. Firoozeh Mirzaee and if 6 months have passed since the publication of the results.
Comments