Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the effect of Auricular point acupressure and body acupressure on the pain score and the active phase duration of first stage of labor

Protocol summary

Study aim

1. Comparison of the mean score of pain during the first stage of labor in 4 and 10 cm dilatation in three groups (acupressure, acupressure, control) 2. Comparison of the mean active phase duration of the first stage of labor in the three groups (acupuncture, acupressure, control)

Design

Clinical trials with control group, hospital-based, with parallel, double-blind, randomized groups

Settings and conduct

The stages of the study: 1- Obtaining permission from the Ethics Committee and the clinical trial code after the approval of the proposal, obtaining the necessary letters for attendance at the center (Kowsar Hospital in Qazvin) 2- Selection of contributors and random allocation in study groups: Initially, pregnant women who have criteria for admission to study at the time of admission will be explained in terms of study objectives and methodology, and if they wish to participate in the research, written consent is obtained from them. Then, based on the predetermined allocation sequence described below, women are divided into three groups: acupuncture, acupressure, and routine control. 3. Evaluation of the pain of all participants at the peak of uterine contraction in 4 cm dilatation of the cervix. 4- Performing intervention in different groups 5- In 10 cm dilatation, the pain rate is measured in all the participants in the three groups. Also, in order to study the duration of the active phase of labor in the groups, the start and end times of the first phase of the labor are recorded in the questionnaire, and the difference between these two times indicates the duration of this stage. (Evaluating the consequences of the type of blinding intervention) 6. Analysis of findings (data analyzer becomes blinded to grouping of patients)

Participants/Inclusion and exclusion criteria

inclusion criteria: PrimiGravida 19-35 years Low risk pregnancy: gestational age between 37-42 weeks; singleton pregnancy; cephalic presentation; no prior medical or surgical complication; height more than 150 cm Having 3-4 cm cervical dilatation Exclusion criteria: No intention to participating in the study Having analgesic drugs 3 hours prior to or during intervention Induction or augmentation of labor

Intervention groups

1- Auricular acupressure 2- body acupressure 3- control with routine care

Main outcome variables

The severity of labor pain in the active phase of the first stage of labor; the duration of the active phase of the first stage of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038789N1**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **prospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

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Zainab Alimoradi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-11, 1396/12/20
Expected recruitment end date
2019-02-19, 1397/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of Auricular point acupressure and body acupressure on the pain score and the active phase duration of first stage of labor

Public title
comparing the effect of Auricular and body acupressure on the pain and the duration of first stage of labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
PrimiGravida 19-35 years Low risk pregnancy: gestational age between 37-42 weeks; singleton pregnancy; cephalic presentation; no prior medical or surgical complication; height more than 150 cm Having 3-4 cm cervical dilatation
Exclusion criteria:
No intention to participating in the study Having analgesic drugs 3 hours prior to or during intervention Induction or augmentation of labor
Age
From **19 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method used to random assignment of participants among groups. For this purpose, Assignment sequence will be written. Given that the three groups will be studied, 6 blocks are used. Each letter is assigned to a group (e.g. A: auricular acupressure, B: body acupressure, C: control with routine care). In this way, all possible states that 6 patients can be split evenly between three treatments are written and numbered as below: 1-AABBCC 2-ABACBC 3-AABCBC 4-BAABCC 5- CBACBA 6- … The next step is to select randomly amongst these different blocks for each group of six participants that are recruited. The random selection will be done using a list of random numbers generated using statistical software SPSS. By writing the contents of the blocks for those numbers (as long as the prescribed sample size is obtained), the random allocation sequence is determined. For example, if the numbers obtained are 4, 1, 1, 3 and …, the assignment sequence will be as follows: BAABCC AABBCC AABBCC AABCBC Then, in the opaque sealed envelopes, the type of intervention is written by the assignment sequence and envelopes are encoded. Questionnaires are also encoded in sequence. In this case, the questionnaire with the same code will be completed for the person receiving the code 1 intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present study, due to the type of intervention, there is no possibility of the participant blindness and the person providing the intervention. However, to observe blindness when collecting information, one of the contributors performs the intervention plan and the other partner who does not know about the intervention will collect the data. Finally, after analyzing the questionnaires and entering them in SPSS-16, data analysis will be done. After analyzing data, the group code will be specified. Therefore, the person analyzing the findings of the study will also be blind to this grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee on Bioethics in Qazvin University of Medical Sciences
Street address
Bahonar blevard, Qazvin university of Medical Science, School of Nursing & Midwifery
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2018-01-29, 1396/11/09
Ethics committee reference number
IR.QUMS.REC.1396.416

Health conditions studied

1

Description of health condition studied
active phase of the first stage of labor
ICD-10 code
O80.0
ICD-10 code description
Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description
labor pain severity
Timepoint
Before intervention in dilatation 4 cm, after intervention in dilatation 10 cm
Method of measurement
Visual Scale of Pain

2

Description
Duration of active phase of first stage of labor
Timepoint
Record the beginning and end of the first stage of labor
Method of measurement
minutes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: auricular acupressure
Category
Other

2

Description
Intervention group: body acupressure
Category
Other

3

Description
Control group: Routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital- Qazvin
Full name of responsible person
Zainab Alimoradi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zainab Alimoradi
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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Zainab Alimoradi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
reproductive health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Title and more details about the data/document
Information about the original outcome is shared

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
All researchers in the field of health and medical science can apply for data.

Under which criteria data/document could be used
A new analysis of the data can only be done by explaining the reasons for the request for such an analysis and with the knowledge of the researcher

From where data/document is obtainable
To receive the data, you can contact the person responsible for this clinical trial (Zainab Alimoradi) at z.alimoradi@qums.ac.ir.

What processes are involved for a request to access data/document
After receiving the application for having a data file and obtaining permission from the university vice chancellor, the data file is shared.

Comments