

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

Name

Zainab Alimoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3333 6003

Email address

z.alimoradi@qums.ac.ir

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

AgeFrom **19 years** old to **35 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget 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 blvard, 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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Bahonar blvard, Qazvin university of Medical Science, School of Nursing & Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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