

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparing the effect of acupressure in the point LI-4 with or without ice on the pain and anxiety levels, stress during labor: a randomised ocontrolled Trial and a meta-analysis

Protocol summary

Study aim

Determination the effect of acupressure with or without ice on pain labor and anxiety during labor

Design

At the beginning sampling is with access method postpartum women, they will then be randomly assigned to one control and tow intervention groups

Settings and conduct

This study is an experimental interventional study with pretest and post test design and implemented in babak city valiasr hospital

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1: Age between 15_49 years 2: Being primi parous; 3: Having physical and mental health 4: 4 cm cervix dilatation and having at least two three uterine contractions in ten minutes 5: Literacy understanding numbers 6: Gestational age 38 to 40 weeks, 7: Singleton pregnancy 8: Cephalic presentation; 9: Readiness and satisfaction to participate in the research. Exist: 1: Threatened abortion, 2: Non-cephalic presentation or had more 2 cesarean section, 3: Intrauterine death, 4: Placentaprevia, 5: Breech presentation, 6: gestational diabetes, 7: Hyperion disorder (preeclampsia and et al), 8: if had a systemic disease during pregnancy 9: (if had a psychological disorder)

Intervention groups

The intervention group 1: In the acupressure group, 4 cm dilatation of the cervix was performed for half an hour and beginning of any uterine contraction by a researcher right hand thumb on the LI 4 region in the right hand side of patient. The intervention group 2: in the ice bag group, for half an hour, during each contraction, the point between the two metacarpal thumb and finger pointed called the hugo area LI_4, was massaged in the right hand and left hand of patient with a small bag of ice The intervention group 3: in the control group, only the touch of the throat without a bag of ice was touched

Main outcome variables

The pain, stress and anxiety during labor in primiparous women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180314039095N1**

Registration date: **2019-08-28, 1398/06/06**

Registration timing: **retrospective**

Last update: **2019-08-28, 1398/06/06**

Update count: **0**

Registration date

2019-08-28, 1398/06/06

Registrant information

Name

Fatemeh Esmaeilnejadhasaroeie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3414 6124

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupressure in the point LI-4 with or without ice on the pain and anxiety levels, stress during labor: a randomised ocontrolled Trial and a meta-analysis

Public title

Comparing the effect of acupressure in the point LI-4 with or without ice on the pain and anxiety levels during labor

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Being primiparous Having physical and mental health 4 cm dilatation and having at least two to three uterine contractions in ten minutes Literacy understanding numbers Gestational age 38 to 40 weeks Singleton pregnancy Cephalic presentation

Exclusion criteria:

Being multiparous Illiteracy Gestational age less than 37 weeks and more than 40 weeks Several pregnancies

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

After selecting the sample from the available sampling method, we divide them into a simple randomized draw metod into two groups of intervention and control.

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 Kerman University of Medical Sciences

Street address

Nursing and Midwifery Collage

City

Kerman

Province

Kerman

Postal code

7419476196

Approval date

2017-12-21, 1396/09/30

Ethics committee reference number

IR. KMU.REC.1396.1655

Health conditions studied**1****Description of health condition studied**

Anxiety and pain during labor

ICD-10 code

O00_O99

ICD-10 code description

بیماری های بارداری، زایمان و نازایی

Primary outcomes**1****Description**

Pain labor

Timepoint

Before the intervention and after the completion of the intervention

Method of measurement

Visual analog scale Questionnaire

Secondary outcomes**1****Description**

Stress and anxiety

Timepoint

Before the intervention and after the intervention is completed

Method of measurement

Questionnaire spilberger

Intervention groups**1****Description**

The intervention group 1 : with his thumbs on the Acupressure LI 4 point, both hands were rotated in the clockwise directio.

Category

N/A

2

Description

Intervention group 2 : using a piece of ice with the fingers her thumbs on the Acupressure LI 4 point were both rotated in the clockwise direction.

Category

N/A

3

Description

Control group: only the two handed fingers touched during uterine contraction.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Shahrababak Hospital Kerman University of Medical Sciences

Full name of responsible person

Arash Sharifian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamid Reza Rashidi Nezhad

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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

Firoze Mirzaee

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Esmaeilinejad Hasaroeih

Position

Master degree Student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

Haftbagh Alavi

City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable