Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 towintervention 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 throut 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
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Name of organization / entity
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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
Ooo _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 thumps 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 Shahrbabak Hospital Kerman University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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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
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Assistant Professor
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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