Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of LI4, H7 and SP6, Neima acupressure on the pain severity and duration of delivery in Nulliparous women

Protocol summary

Study aim
The effect of acupressure on the pain severity and duration of delivery in Nulliparous women

Design
144 Pregnant women who candidate for vaginal delivery and having study inclusion criteria, selected by a conveinence sampling method. They were randomly assigned to two groups of intervention and control with fourth block (two groups 72). The trial group received acupressure aimed at reducing labour pain. At the end measurement of the severity of pain in the first and second stage of labor with Visual Analogue Scale, in order to determine the effect of acupressure on the severity of labour pain.

Settings and conduct
144 Pregnant women who candidate for vaginal delivery and having study inclusion criteria, will be participated in the study after completing written consent. Then participates are randomly assigned to two groups of intervention and control and complete the checklist of demographic and pregnancy characteristics (two groups 72).

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Pregnant women with 19 to 35 years old, nulliparity, gestational ages between 42-37 weeks, Singleton and Low-risk pregnancies. Exclusion criteria: Oxytocin administration for induction or estimulation of labor, the tendency of mother to use analgesic medications, unreliable embryonic cardiac rhythm.

Intervention groups
In the intervention groups, in addition to the usual childbirth room cares, acupressure pads will be placed on the SP6 and NEIMA points. Then will be connected to the TENS device and the low frequency is applied to stimulate the acupressure points. From the dilatation of 8 centimeters, the points are changed to H7 and LI4 points on the hand, and this time the stimulation will be continued with high frequency. Control groups will receive usual childbirth room cares and aromatherapy without any intervention.

Main outcome variables
Labour pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171203037731N1**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date
2018-06-06, 1397/03/16

Registrant information

Name
Zahra Mehri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of LI4, H7 and SP6, Neima acupressure on the pain severity and duration of delivery in Nulliparous women

Public title

the effect of acupressure on the Pain Severity of delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Nuliparous women 19 to 35 years old Gestational ages between 42-37 weeks Singleton and Low-risk pregnancies

Exclusion criteria:

Oxytocin administration for induction or estimolation of labor The tendency of mother to use analgesic medications unreliable embryonic cardiac rhythm

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

144 pergnant women with labor pain selected by a convenience sampling method. They were randomly assigned to two groups of intervention and control with fourth blocks (two groups 72).

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 Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin University of Medical Sciences.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.QUMS.REC.1396.395

Health conditions studied

1

Description of health condition studied

Labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain severity of delivery in Nulliparous women

Timepoint

Before and after intervention

Method of measurement

Visual Angle Scale

Secondary outcomes

1

Description

Duration of delivery in Nulliparous women

Timepoint

After intervention

Method of measurement

Digital clock

Intervention groups

1

Description

Intervention group: In the intervention groups, in addition to the usual childbirth room cares, after being in good position, acupressure pads will be placed on the SP6 and NEIMA points on one side the foot. Then will be connected to the TENS device and the low frequency is applied to stimulate the acupressure points. The device will be available to the mother. From the dilatation of 8 centimeters, the points are changed from the SP6 and NEIMA on foot to the H7 and LI4 points on the hand, and this time the stimulation will be continued with high frequency.

Category

N/A

2

Description
Control group: Control groups will receive usual childbirth room cares and aromatherapy without any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Razi Hospital
Full name of responsible person
Fatemeh Ranjkesh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peymani
Street address
Dept. of research Qazvin University of Medical Sciences Shahid Beheshti, Ave' 3415613911 Qazvin' IRAN
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apeymani@qums.ac.ir
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
Fatemeh Ranjkesh
Position
Instructor
Latest degree
Master
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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
Not applicable

Title and more details about the data/document
All the data have code to identify.

When the data will become available and for how long
In 2019

To whom data/document is available
Qazvin University of Medical Sciences

Under which criteria data/document could be used
By confirmation of Qazvin University of Medical Sciences

From where data/document is obtainable
Qazvin University of Medical Sciences

What processes are involved for a request to access data/document
Refer to Qazvin University of Medical Sciences or sending email to franjkesh@qums.ac.ir

Comments