

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 convenience 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 stimulation 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

Country

Iran (Islamic Republic of)

Phone

+98 28 3369 8724

Email address

z.mehri@qums.ac.ir

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:
Nulliparous women 19 to 35 years old Gestational ages between 42-37 weeks Singleton and Low-risk pregnancies
Exclusion criteria:
Oxytocin administration for induction or stimulation 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 pregnant 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

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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

Fatemeh Ranjkesh

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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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