

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

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

Protocol summary

Study aim

The effect of acupressure on the Anxiety 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(n= 72) and control(n=72) with fourth block.The trial group received acupressure aimed at reducing on the Anxiety of delivery. At the end measurement of the Anxiety of delivery in the first and second stage of labor with Spielberger questionnaire, in order to determine the effect of acupressure on the Anxiety of delivery.

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.

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 estimation 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 delivery 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 delivery room cares and aromatherapy.

Main outcome variables

Anxiety of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037731N2**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

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

2018-03-11, 1396/12/20

Expected recruitment end date

2018-10-12, 1397/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of LI4, H7 and SP6, Neima acupuncture on the Anxiety of delivery in Nulliparous women

Public title

the effect of acupuncture on the Anxiety 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 fetus cardiac rhythm

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

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

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2018-02-27, 1396/12/08

Ethics committee reference number

IR.QUMS.REC.1396. 479

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety of delivery

Timepoint

Before and after intervention

Method of measurement

Spielberger state questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention groups, in addition to the usual childbirth room cares, after being in good position, acupuncture 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 acupuncture 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

Rehabilitation

2

Description

Control group: Control groups will receive usual childbirth room cares and aromatherapy without any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Razi Hospital

Full name of responsible person

FatemehRanjkes

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3323 7268

Email

Franjkesh@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Qazvin University of Medical Sciences Shahid
Beheshti, Ave' 3415613911 Qazvin' IRAN

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 7006

Email

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

FatemehRanjkes

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3323 7268

Email

franjkesh@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

FatemehRanjkes

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3323 7268

Email

franjkesh@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

FatemehRanjkes

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3323 7268

Email

franjkes@qums.ac.ir

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

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

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 franjkes@qums.ac.ir

Comments