Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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 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)

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+98 28 3369 8724

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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 acupressure on the Anxiety of delivery in Nulliparous women

Public title
the effect of acupressure on the Anxiety 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 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 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
Qazvin University of Medical Sciences, Bahonar Blvd.
City
Qazvin
Province
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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, 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
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
FatemehRanjkesh
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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
Qazvin University of Medical Sciences Shahid Beheshti, Ave' 3415613911 Qazvin' IRAN
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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
FatemehRanjkesh
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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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
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 franjkesh@qums.ac.ir
Comments