Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Saninjiao acupressure with combined Sp6 , LI4 acupressure on labor pain intensity in nulliparous women

Protocol summary

Study aim
Evaluation of pain intensity in the combined Saninjiao and Hob-Gou acupressure with Saninjiao point

Design
Three parallel groups of clinical trials with control group, blinded participants, randomized, with a sample size of 35 persons per group

Settings and conduct
Imam Reza Lar Hospital (Labor and delivery ward). Participants are unaware of the type of intervention they take.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Single pregnancy, gestational age 37-42 weeks, Membrane intact , having at least 4 cm cervical dilatation and having at least 3 contractions per 10 minutes, cephalic presentation, spontaneous contractions .Exclusion criteria: High risk pregnancy, vaginal bleeding, poor obestetric history, large baby

Intervention groups
The curent resarch is a three-group study in which the group A received massage from the Saninjiao point and group B combined massage and the C group touches the Saninjiao point. At 4 cm dilatation,with the bigening each contraction the intervention will begin . In group A, acupressure will occurs at saninjiao point during the utrine contraction, in group B, with the onset of the first contraction, the point of Saninjiao in both parties Slowly pressed, then during the next contraction, the Hugo point on both hands is pressed in the same way during contractions, and again the Saninjiao point is pressed on both legs during the contractions, and again the Hugo point in both hands is the same The order is squeezed. In the c group, the touch of the Saninjiao point occurs, and this continues for up to 20 minutes only during contractions.

Main outcome variables
labor pain intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180407039223N1**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**
Update count: **0**

Registration date
2018-08-03, 1397/05/12

Registrant information
Name
Leila Bagheri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-22, 1397/03/01
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of Saninjiao acupressure with combined Sp6 , LI4 acupressure on labor pain intensity in nulliparous women

Public title
The Effect of Combined Massage of Hugo and Saninjiao Points on the labor pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Singleton pregnancy Gestational age 37-42 weeks Intact fetal membrane Having at least 4 cm of dilatation Have at least 3 contractions in 10 minutes Cephalic presentation
Exclusion criteria:
High risk pregnancy Poor Ob history Vaginal bleeding Large baby Cephalopelvic disporportion 145 cm height and lower Having lesion at Saninjiao and Hugo points Having any problems leading to the mother's inability to communicate
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Considering that in our study, there are three control groups, Saninjiao point acupressure and a combination massage, block sampling (six)will be used. Previous envelopes are considered by the methodologist (in the sixth block) and in Each of these envelopes has a letter A or B or C. A total of 105 envelopes will be available to qualified participants. At the time of entering the research environment, choose one of the pre-prepared envelopes for the patient himself and determine which of the groups A, B, C will be placed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
If the patient uses analgesics or oxytocin, they will be excluded.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahroud University of Medical Sciences
Street address
Hafte Tir Square
City
shahroud
Province
Semnan
Postal code
73947-36147
Approval date
2017-06-20, 1396/03/30
Ethics committee reference number
IR.SHMU.REC.1396.43

Health conditions studied

1

Description of health condition studied
Labor pain intensity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity score on VASA scale
Timepoint
Before the intervention, immediately, one hour and two hours after the intervention and in the second stage of labor
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Saninjiao acupressure ،An example of a non-pharmacological method is acupressure, where acupuncture points are stimulated by hands, fingers, thumbs, or small beads. This method acts according to the gate control theory where burning, massaging, and scratching can stimulate the large fibers responsible for transmitting nerve impulses to the spinal cord. A sustained stimulation can keep the gates of pain transmission closed, which may result in decreased pain. On the other hand, the stimulation of acupressure points using heat, needles, or pressure causes the release of endorphins.Acupressure was applied by placing index

and middle finger of both hands on both legs at the same time from the beginning to the end of the contraction. The researcher massage the acupressure points so that the patient feet will numb .At the end of the contraction, acupressure was stopped .This process continued for 20 minutes only during the uterine contractions (the number of contractions varied based on each patient. During the acupressure procedure, uterine contractions and fetal heart rate will monitored.

Category

Treatment - Other

2

Description

Intervention group: Combined Hugo and Saninjao acupressure. An example of a non-pharmacological method is acupressure, where acupuncture points are stimulated by hands, fingers, thumbs, or small beads. This method acts according to the gate control theory where burning, massaging, and scratching can stimulate the large fibers responsible for transmitting nerve impulses to the spinal cord. A sustained stimulation can keep the gates of pain transmission closed, which may result in decreased pain. On the other hand, the stimulation of acupressure points using heat, needles, or pressure causes the release of endorphins.Acupressure was applied by placing index and middle finger of both hands on both legs at the same time from the beginning to the end of the contraction. At the end of the contraction, pressure was gradually reduced and acupressure was stopped during the resting phase . with the beginning the contraction the Hugo point on both hands is pressed in the same way during contractions, and again the Saninjiao point is pressed on both legs during the contractions, and again the Hugo point in both hands is the same . The order is squeezed. This process continued for 20 minutes only during the uterine contractions (the number of contractions varied based on each patient).During the acupressure procedure, uterine contractions and fetal heart rate will monitored.

Category

Treatment - Other

3

Description

Control group: Saninjiao Point touch, With the beginning to the end of the contraction the touch of the Saninjiao point occurs . At the end of the contraction, touch was stopped during the resting phase and this continues for up to 20 minutes only during contractions. During the touch procedure, uterine contractions and fetal heart rate will monitored.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Leila Bagheri

Street address

Dadman Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

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Shahroud

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Postal code

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Web page address

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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

Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Leila Bagheri

Position
Candidate PhD of reproductive health

Latest degree
Master

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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