

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 obstetric history, large baby

##### Intervention groups

The current research 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 beginning of each contraction the intervention will begin . In group A, acupressure will occur at the saninjiao point during the uterine contraction, in group B, with the onset of the first contraction, the point of Saninjiao in both parties is 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)

##### Phone

+98 71 5225 1581

##### Email address

leilabagheri94@shmu.ac.ir

##### 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 disproportion 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

Hafta 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 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. 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

**City**

Larestan

**Province**

Fars

**Postal code**

7431843953

**Phone**

+98 71 5224 1001

**Email**

leilabagheri1352@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad Hasan Emamian

**Street address**

Hafte-Tir Square

**City**

Shahroud

**Province**

Semnan

**Postal code**

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**Fax**

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**Email**

vcr@shmu.ac.ir

**Web page address**

<http://www.shmu.ac.ir/fa>

**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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Leila Bagheri

**Position**

Candidate for PhD reproductive health

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Leila Bagheri

**Position**

PhD Candidate 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