

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the Effect of Acupressure in LI4 and SP6 Points on Post-Cesarean Section Pain Severity in women

Protocol summary

Study aim

Comparison of the effect of acupressure in compression points LI4 and SP6 on severity of post-cesarean pain in women referred to Rafsanjan niche nursing home in 1396

Design

In this study, 90 women who are referred to the Rafsanjan Nifr-e Nafs Hospital for elective cesarean section and who have criteria for entering the study will be selected. Participants will be randomly divided into three groups of SP6 intervention or LI4 interventions based on pre-test and pre-test scores. Or control group will be divided so that the classes will be based on the grade of pain 4-6 in one class and the pain of 7-10 in the other category.

Settings and conduct

At the first time, complete recovery of the sensitivity and sensation of the lower limbs and before receiving the first dose of pain, the severity of pain will be measured by the Visual Analog Scale (VAS) scale. Samples will be divided into three groups based on pre-test pain severity. Then, in an intervention group at the SP6 point and in the intervention group at the point of LI4, the two-way pressures for 10 seconds and 2 seconds of rest for 20 minutes will be applied sequentially. The amount of pressure applied should be such that the samples feel warm and have mild pain and pressure. Acupressure will be carried out by one of the researchers who has sufficient training in this regard. And in the control group, the touch will be applied without applying pressure with the same pattern when used in the intervention groups used at the same points. The control group will be divided into two groups, and in a touch group at the SP6 point and in the other group, the touch will be at the LI4 point. It should be noted that for all three groups of treatments and routine care will be performed. Then, the severity of pain is measured using the VAS scale immediately (within 5 minutes after the intervention) and 60 minutes after touch and pressure, in order to minimize the effect of the bias curve bias, which means

that nine samples No one who measures the severity of pain will not know how to allocate samples to the research (intervention or control) groups.

Participants/Inclusion and exclusion criteria

1. Term pregnancy 2. No previous experience of acupressure 3. Having ages 45-18 years 4. Lack of a lesion at the site of the practice of pressure or touch 5. No addiction 6. Failure to have speech and hearing ability 7. Not having known psychiatric disorders 8. Not having crises such as divorce, loss of loved ones, immigration or over the past 6 months 9. Elective cesarean section as a criterion for entry Unwillingness to cooperate with each research unit during the study 2. Those with acute complications after cesarean section (severe bleeding, embolism, etc.) 3. Those who will need to receive housing during the intervention until the second assessment of the severity of pain will be included in the exit criteria.

Intervention groups

In this study, the effect of acupressure is measured at SP6 and LI4 points in an acupressure group at the SP6 point and in the second group at the LI4 point and in the third group, a touch without pressure in one of these points is performed, so that the touch group, half touch LI4 and the other will receive the touch of the Sp6

Main outcome variables

reducing post-cesarean pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171113037426N1**

Registration date: **2018-01-13, 1396/10/23**

Registration timing: **retrospective**

Last update: **2018-01-13, 1396/10/23**

Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34351079

Email address

afh1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Acupressure in LI4 and SP6
Points on Post-Cesarean Section Pain Severity in women

Public title

The Effect of Acupressure on Cesaerian Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1. Term pregnancy 2. No previous experience of acupressure 3. Having ages 45-18 years 4. Lack of a lesion at the site of the practice of pressure or touch 5. No addiction 6. Failure to have speech and hearing ability 7. Not having known psychiatric disorders 8. Not having crises such as divorce, loss of loved ones, immigration or over the past 6 months 9. Elective cesarean section Exit criteria: 1-Unwillingness to cooperate with each of the research units during the study 2. Those with acute complications after cesarean section (severe bleeding, embolism, etc.) 3- Those who during the intervention until the second assessment of the severity of pain will necessarily need to receive the housing

Exclusion criteria:

Exit criteria:2. Those with acute complications after cesarean section (severe bleeding, embolism, etc.)3- Those who during the intervention until the second assessment of the severity of pain will necessarily need to receive the housing

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 90 women among all women who give birth to cesarean births in Rafsanjan nurseries will be selected in a targeted manner and based on the criteria for entering and leaving the study. Then, they are randomly classified into three groups (two groups of intervention and one control group). So that both groups are consistent with the severity of pain after cesarean section. The first entry in the groups will be random and the rest will be based on the total number of samples in each class. Sampling will continue until the sample size reaches the target. Considering the fact that several factors can affect the pain such as the number of delivery, type of BMSI, age, etc., but ultimately the effect of these factors is measured on the pre-test pain intensity. Therefore, the matching of the three groups based on pre-test pain intensity is considered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Nine specimens, not individuals who measure pain intensity, will not know how to allocate samples to research groups (intervention or control). And to all the sample, even those in the control group will be told that intervention or touch will reduce pain

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Rafsanjan Imam Ali Boulevard, Central Organization

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Women undergoing cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by emergency caesarean section

Primary outcomes

1

Description

post caearian section

Timepoint

Immediately and hour after study

Method of measurement

for vas scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group 1- Acupuncture at Hugo Point (LI4): These subjects, after being fully conscious while lying back, The researcher will use the thumb of both her hands at the Hugo Point on either side of the mother, for 20 consecutive periods of 10 seconds pressure and 2 seconds of resting. The Hugo point is one of the most important points in the intestinal meridian that located behind the hand between the first and second metacarpal bones and at the base of second metacarpal. The pressure will be deeply and applied the researcher nails are made to change color and the mother feels warm and has mild pain and pressure

Category

Treatment - Other

2

Description

Intervention group: 2- Acupressure at the Saninjao Point (SP6): These subjects, after being fully conscious and returning the sensation of lower limbs while lying back, The researcher will be placed at the bottom of the mother foot and face-to-face using the thumb of both hands at the Saninjao Point on either side of the mother will made intervention for 20 consecutive periods of 10 seconds pressure and 2 seconds of resting. SP6 point is located in the meridian of the spleen, and is located at 4 fingers above the inner ankle behind the posterior margin of the tibia. The pressure will be applied deeply

until the researcher nails are made to change color and the mother feels warm and mild pain and pressure.

Category

Treatment - Other

3

Description

Control group: After the consciousness and the return of sensation in the lower limbs of these subjects, while lying behind, the researcher will be placed face- to face to them, and in half of them at the Hugo point, and in the other half at the Saninjao point, will touch on either side of the mother without pressure for 20 seconds .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nafe Rafsanjan Maternity Hospital

Full name of responsible person

طیبه نگاهبان بنایی

Street address

Rafeshjan Shohada Street, Nafe Rafsanjan Maternity Hospital Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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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
 Rafsanjan 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

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Person responsible for updating data

Person responsible for general inquiries

Contact
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Person responsible for scientific inquiries

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Latest degree
 Ph.D.
Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available