Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of effectiveness of acupressure six spleen and Hugo point on the severity of postpartum pain

Protocol summary

Study aim
The comparison of effectiveness of acupressure six spleen and Hugo point on the severity of postpartum pain

Design
A clinical trial with two intervention groups and no control group, randomized in parallel and one-sided, phase 3 on 68 primiparous pregnant women. For randomization, the block randomization method will be used using blocks of 6.

Settings and conduct
This clinical trial study will be conducted on 68 eligible primiparous pregnant women referred to Farabi Hospital in Malekan city after obtaining the necessary permits. Mothers will be examined in the post-partum department at least two hours and at most three hours after delivery. The pain intensity of mothers who have given birth naturally will be recorded with a pain ruler. People in one of the two categories of moderate (score -4-6) or severe (score 7-10) using the visual pain scale are selected by the available method and then randomly divided into two groups. intervention group (acupressure point 6 spleen) Intervention group (acupressure point of Hugo

Participants/Inclusion and exclusion criteria
Inclusion Criteria: being primiparous, being in the first trimester of pregnancy, not having previous experience with acupressure, not having a lesion at the place where acupressure is applied, not having problems in the ability to speak, hear and see, not being addicted, not having known mental disorders, not having Crises such as divorce, loss of loved ones, immigration or... during the last 6 months. Exclusion criteria: Unwillingness to cooperate with any of the research units during the study, occurrence of complications after normal delivery (heavy bleeding, embolism, etc.) The usual pain reliever in case of severe back pain is diclofenac suppository 100 mg).

Intervention groups
Intervention group (acupressure point 6 spleen)
Intervention group (Hugo point acupressure)

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220910055926N1**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date
2022-09-13, 1401/06/22

Registrant information

Name
Saba Mohammadghasemnezhadmaleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3828 2101

Email address
sabamgm1992@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effectiveness of acupressure six spleen and Hugo point on the severity of postpartum pain

Public title

The comparison of effectiveness of acupressure six spleen and Hugo point on the severity of postpartum pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous Term of pregnancy No previous experience of acupressure Not having a lesion at the place of applying acupressure Having no problems in speech, hearing and vision No addiction Not having known mental disorders Not having crises such as divorce, loss of loved ones, immigration or... during the last 6 months.

Exclusion criteria:

Reluctance to cooperate Complications after natural delivery (heavy bleeding, embolism, etc.) There is a need to receive additional painkillers outside of the usual department during the study (the usual painkillers of the department in case of severe back pain, diclofenac 100mg suppositories).

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method using 6 blocks will be used. A third person who is not involved in the process of diagnosing and evaluating patients will create a random sequence using the site: https://www.sealedenvelope.com and based on the sample size, 12 blocks of 6 will be created. Each patient will be given a unique code that can be created on this site.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, in order to prevent bias of the interventionist, data collection is done by another person who does not perform the intervention, who does not know about the allocation of the participants in the research groups. In the current study, there is no possibility of blinding the researcher because he is aware of the acupressure points and the stimulation of the points is done by him, but since the participants do not have previous experience of acupressure and do not know where the two desired points are located, the study is a Sue is blind. Also, the information analyst does not know about the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah Province, Kermanshah, Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

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Approval date

2022-08-23, 1401/06/01

Ethics committee reference number

IR.KUMS.REC.1401.251

Health conditions studied

1

Description of health condition studied

Severity of labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of labor pain

Timepoint

Before, immediately after and one hour after the intervention

Method of measurement

Visual Analouge Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Spleen point 6 acupressure: Acupressure intervention at spleen point 6 and intervention at Hugo point are applied bilaterally, in periods of 10 seconds of pressure and 2 seconds of rest for 20 minutes consecutively. The amount of applied pressure is such that the samples feel warm and have slight pain and pressure. Spleen pressure point 6 is in the Spleen meridian and is located 5 cm above the inner angle of the tibia, and the location of the Hugo point is anatomically in the back of the hand between the first and second metacarpal bones and almost along the radial bone.

Category
Treatment - Other

2

Description
Hugo point acupressure: Acupressure intervention at spleen point 6 and intervention at Hugo point are applied bilaterally, in periods of 10 seconds of pressure and 2 seconds of rest for 20 minutes consecutively. The amount of applied pressure is such that the samples feel warm and have slight pain and pressure. Spleen pressure point 6 is in the Spleen meridian and is located 5 cm above the inner angle of the tibia, and the location of the Hugo point is anatomically in the back of the hand between the first and second metacarpal bones and almost along the radial bone.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi Hospital, Malekan City

Full name of responsible person
Saba Mohamad Ghasem Nezhad Maleki

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Farabi Malekan hospital; Shahriar Blvd, Malekan, East Azerbaijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Sosan Heidarpour

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Kermanshah, Shahid Beheshti Boulevard, Kermanshah University of Medical Sciences

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s.heydarpour1394@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Saba Mohamad Ghasem Nezhad Maleki

Position
Student

Latest degree
Bachelor

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)
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