

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of acupuncture on reducing pain after cesarean section under intrathecal anesthesia

Protocol summary

Study aim

Investigating the effect of acupuncture on reducing pain after caesarean section surgery under intrathecal anesthesia

Design

Clinical trial with control group, double-blind, randomized on 60 patients

Settings and conduct

This study is a double-blind clinical trial with an intervention and control group, after obtaining the necessary permits from the research council and ethics committee, on patients who referred to the OR of Imam Khomeini Hospital in Ahvaz in 1401 for elective caesarean section, will be done. Patients are blinded to the type of intervention. Pain intensity is measured by a trained anesthetist in recovery who is not aware of the type of intervention. At first, using the available sampling method, all patients who are candidates for cesarean surgery will be selected and divided randomly (block of four) into intervention and control groups. In the intervention group, after the onset of pain during recovery, acupuncture is performed by a trained anesthetist for 20 minutes at LI4 and PC6 points, which are located on the back of the hand and at the anterior level of the middle forearm and in the control group, in case of pain, routine painkiller treatment (25 mg pethidine) is injected.

Participants/Inclusion and exclusion criteria

Entry criteria include: Age 18-45 years, no previous experience of using acupuncture, no scars, bruises, itching at the needle insertion site, no sensitivity to fake jewelry and steel watches. Exclusion criteria include: emergency surgery, heavy intraoperative bleeding, use of any kind of painkillers before and during the operation, unusual prolongation of the operation

Intervention groups

In the intervention group, at LI4 and PC6 points, acupuncture is performed by a trained anesthesiologist for 20 minutes. The control group receives routine

painkiller treatment (25 mg of pethidine) in case of moderate and severe pain.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220806055627N1**

Registration date: **2023-01-27, 1401/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-27, 1401/11/07**

Update count: **0**

Registration date

2023-01-27, 1401/11/07

Registrant information

Name

Mohammad Hossein Kadkhodaie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupuncture on reducing pain after cesarean section under intrathecal anesthesia

Public title

The effect of acupuncture on reducing pain after cesarean section under anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA class I and II Age 18-45 years Women candidates for elective cesarean surgery

Exclusion criteria:

She had history of using acupuncture having scars, bruises, itchiness at the place where the needle is inserted Being allergic to fake jewelry and steel watches

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were initially selected as available and then randomly (block of four: two people in the intervention group and the next two people in the control group) will be divided into two groups of 30 people, intervention and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blinded to the type of intervention. Pain intensity is measured by an anesthesiologist trained in recovery who is not aware of the type of intervention.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Street address

University City, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, ground floor.

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.067

Health conditions studied**1****Description of health condition studied**

Pain after surgery

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes**1****Description**

Pain

Timepoint

Immediately after the intervention, 30, 60 and 120 minutes after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After surgery, with the onset of pain, at point LI4, which is located in the middle of the angle between the first and second bones of the palm, between the thumb and Weber's finger on the back of the hand and at point PC6, which is located on the anterior surface of the forearm, 4 cm above the transverse fold of the hand between the Palmaris longus and Flexor Carpi radialis tendons, Acupuncture is performed by a trained anesthesiologist for 20 minutes.

Category

Treatment - Other

2**Description**

Control group: In recovery, with the onset of pain, they will receive routine analgesic treatment (25 mg pethidine).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Mohammad Hosein Kadkhodaie

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

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Hosein Kadkhodaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Not applicable

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