Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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
Khouzestan
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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Department of Anesthesiology, General Operation room, Second Floor, Imam Khomeini Hospital, Shahid Ahvazian St., Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
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Anesthesiology
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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