

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effect of Acupuncture on Hemodynamic_profile after Spinal Anesthesia during Cesarean Section

Protocol summary

Study aim

The survey of the effect of acupuncture on the hemodynamic-profile after spinal anesthesia for cesarean section

Design

Clinical trial with a control group, double blinded with randomized parallel groups

Settings and conduct

In the general hospital pregnant women candidates for elective cesarean section with spinal anesthesia enter the study. Before spinal anesthesia, in the first group, electroacupuncture is performed for 10 minutes. In the placebo group, leads attached to the points indicated and electroacupuncture device is not turned on. In the control group BP and PR monitoring is performed without any intervention.

Participants/Inclusion and exclusion criteria

Patients undergoing cesarean section with spinal anesthesia between the ages of 18-45 and the gestational age of 38-39 weeks are included in the study. Patients with preeclampsia/twin or multiple/severe obesity/taking steroids/ diabetes and patients outside the age 18-45 and preterm pregnancy are excluded from the study.

Intervention groups

Patients who meet the conditions for entering the study are in one of three groups (acupuncture/ placebo/ control). In the acupuncture group, both hands at the p6 point before the spinal anesthesia, electroacupuncture are performed for 10 minutes. The placebo group, leads is clinging to the points mentioned and attached to electroacupuncture device but device is not turned on. For the control group only PR/BP is monitored but nothing is performed.

Main outcome variables

Time before intervention up to 5 minutes after spinal anesthesia, Hypotension after spinal anesthesia, bradycardia after spinal anesthesia, need for vasopressor after spinal anesthesia, nausea after spinal anesthesia,

vomiting after spinal anesthesia.

General information

Reason for update

Acronym

EAHSACS

IRCT registration information

IRCT registration number: **IRCT20181011041308N2**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Mahmoud Reza Alebouyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 6136

Email address

alebuieh.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acupuncture on Hemodynamic_profile after Spinal Anesthesia during Cesarean Section

Public title

The Effect of Acupuncture on Hemodynamic_profile after Spinal Anesthesia during Cesarean Section

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with elective cesarean section with spinal anesthesia without a history of disease Age of 18-45 years old Gestational age: 38-39 weeks

Exclusion criteria:

Pregnant women with preeclampsia/high blood pressure/out of range 18-45/gestational age 38-39 weeks diabetes/severe obesity /taking more than 5 mg of prednisone/multiple pregnancy/

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who evaluates the outcome is unaware of the interventions.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2019-05-22, 1398/03/01

Ethics committee reference number

IR.IUMS.FMD.REC.1398.115

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

Hemodynamic profile changes after spinal anesthesia through cesarean section of pregnant women.

ICD-10 code

I95

ICD-10 code description

Hypotension

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

The changes of mean arterial pressure

Timepoint

Before spinal anesthesia and immediately after spinal anesthesia and after 5,10,15,20,25,and 30 minutes respectively after spinal anesthesia

Method of measurement

Non invasive blood pressure

2**Description**

The changes heart rate

Timepoint

Before spinal anesthesia and immediately after spinal anesthesia and after 5,10,15,20,25,and 30 minutes respectively after spinal anesthesia

Method of measurement

HR monitoring

Secondary outcomes

empty

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

Intervention group: in this group the patients are electroacupuncture in p6 point before spinal anesthesia for ten minutes.

Category

Treatment - Other

2

Description

Control group: in this group the leads of electrooccupuncture are attached in p6 point but the device is not turned on .

Category

Other

3

Description

Control group: in this group patients are monitored after and before spinal anesthesia due to the changes of BP and heart rate without doing any actions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul akram hospital

Full name of responsible person

Mahmud Reza Alebuieh

Street address

Rasool Akram hospital. Niayesh ave., Sattarkhan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahmud Reza Aleuieh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Name of organization / entity

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Resident

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Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

information about the main and secondary outcom

When the data will become available and for how long

start the access period immediatly after printing the results

To whom data/document is available

only individuals and academic institutions

Under which criteria data/document could be used

The result of any analysis without harmonization and permission is not published

From where data/document is obtainable

alebuieh.mr@iums.ac.ir

What processes are involved for a request to access data/document

The request from academic university will be answered within ten business days.

Comments