

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

acupuncture effects in the prevention of nausea and vomiting after spinal anesthesia

Protocol summary

Study aim

Determination of the effects of acupuncture in the prevention of nausea and vomiting after cesarean section

Design

Clinical trial with control group, with parallel groups, on 99 patients.

Settings and conduct

This study will be performed in Khatam Al-Anbia Hospital in Shahroud. Group (A) will be treated with acupuncture. To group (b) We will give metoclopramide (10 mg or 15.0 kg / mg ampoule). Group (c) will also be witnesses. Next we will examine nausea and vomiting. The location of the needles will be as follows: GB20: head difference (one number) Shenmen: small triangle above the eardrum (half of the trunk of the upper roof of the eardrum) (2 pcs) Li4: crease between thumb and forefinger tangential to palm (2 pcs) PC6: Wrist crease (2 (2cun finger)) higher than wrist crease adjacent to palmaris longus tendon (2 pcs)

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Patient informed consent, Single pregnancy, Multiparient (after cesarean section) and without any organ disease and Exclusion criteria including a history of recent nausea and vomiting (due to any disease), Noli Parity, History Use of recent anti-nausea, antihypertensive, sedatives and H2 antagonists, history of postoperative nausea and vomiting, substance or drug abuse addicts, and unwillingness to continue cooperation.

Intervention groups

Pregnant mothers will be divided into 3 groups of 33 people. Group (a) will be treated with acupuncture. To group (b) We will give metoclopramide (10 mg or 15.0 mg/kg ampoule). Group (c) will also be witnesses.

Main outcome variables

Prevention of nausea and vomiting after spinal anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049770N1**

Registration date: **2021-01-12, 1399/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-12, 1399/10/23**

Update count: **0**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

Nasim Firouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 8670 5503

Email address

najibfarrokhy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-23, 1398/11/03

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

acupuncture effects in the prevention of nausea and vomiting after spinal anesthesia

Public title

The effect of acupuncture on the prevention of nausea and vomiting after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient informed consent Single term pregnancy Multiparity (second cesarean section onwards) Without any organ disease

Exclusion criteria:

A recent history of nausea and vomiting due to any illness Nulliparity History of taking antiemetic drugs History of taking antihypertensive drugs History of taking sedatives History of postoperative nausea and vomiting Addicts with drug or drug use

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 99

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University-Shahrood branch

Street address

Khatamolanbial Hospital, Tehran Ave

City

Shahrood

Province

Semnan

Postal code

3614871151

Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.009

Health conditions studied

1

Description of health condition studied

Acupuncture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of nausea and vomiting based on questions from the patient

Timepoint

Nausea and vomiting will occur in the first hour in the recovery room and in the second hour in the women's ward.

Method of measurement

Explain the nausea and vomiting to the patient and then ask about the condition

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group will be treated with acupuncture. The location of the needles will be as follows: GB20: head difference (one number) Shenmen: small triangle above the eardrum (hemisphere of the upper roof triangle (2 pcs.) Li4: crease between thumb and forefinger tangential to palm (2 pcs.) PC6: Wrist crease (2 (2cun finger)) above the wrist crease adjacent to Palmaris longus muscle tendon (2 pcs)

Category

Prevention

2

Description

Intervention group 2: This group will be given metoclopramide (10 mg or 0.15 mg per kg body weight)

Category

Prevention

3

Description

Control group: Patients in this group do not receive any medication.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolanbia Hospital

Full name of responsible person

Yousef Kolookhy

Street address

Khatamolanbia Hospital, Tehran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behrooz Yahiaie

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Yousef Kolookhy

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nasim Firoozy

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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