Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of preventive effect of acupuncture with dexamethasone and ondansetron on nausea and vomiting after cesarean section

Protocol summary

Study aim
Evaluation of the effects of acupuncture to prevent vomiting

Design
Clinical Trial with control group, with parallel groups, double blind, randomized, phase 3 on 90 patients. A random number table was used for randomization. The first intervention group is dexamethasone. The second intervention group is ondansetron. The control group is acupuncture.

Settings and conduct
90 Patients are examined in the gynecological surgery ward of Khatam Al-Anbia Hospital in Shahroud. The desired anti-nausea drugs (ondansetron 4 mg or dexamethasone 8 mg) are provided by the anesthesiologist in two groups to the anesthesiologist, who does not know the type of drug, and the drug is injected intravenously into the patient. We want to investigate the effect of acupuncture. PC6 points on both hands are stimulated and inserted once using induction using a special needle, and then the needle is removed from the site. In this study, participants did not know the type of drug and the time of drug injection and the time of acupuncture. Intern as a lead researcher and nurses or anesthesiologist does not know the type of drug. Data collectors do not know when the drugs were injected.

Participants/Inclusion and exclusion criteria
Patients in Class I and II of the American Society of Anesthesiologists (ASA I-II) between the ages of 18 and 65 are included in the study, and patients with contraindications to ondansetron or dexamethasone have a history of taking drugs that interact with ondansetron or dexamethasone Or have a history of ondansetron or dexamethasone allergies, are excluded.

Intervention groups
The anti-nausea drugs (ondansetron 4 mg or dexamethasone 8 mg) are injected into the patients in the first and second intervention groups by anesthesia technicians. In the control group, we should examine the effect of acupuncture.

Main outcome variables
Nausea and Vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210830052344N1**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**
Update count: **0**

Registration date
2021-10-02, 1400/07/10

Registrant information

Name
Milad Johari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 4422 4139

Email address
drmiladjohari.med92@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-15, 1400/06/24

Expected recruitment end date
2021-10-06, 1400/07/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of preventive effect of acupuncture with dexamethasone and ondansetron on nausea and vomiting after cesarean section

Public title

Preventive effects of acupuncture on nausea and vomiting after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All class I and II patients of the American Society of Anesthesiologists (ASA I-II) who undergo cesarean section surgery under general anesthesia They receive opioid medications during surgery

Exclusion criteria:

Patients who have a contraindication to ondansetron or dexamethasone Patients who have a history of taking drugs that interact with ondansetron or dexamethasone Patients who have a history of allergies to ondansetron or dexamethasone Patients who have a mechanical cause for postoperative nausea and vomiting (such as premature obstruction or ileus)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in this study is done by simple randomization method. Randomization based on a single sequence of random allocations is called simple randomization. The randomization unit in this study is individual and the random number table tool is used. Random number table is a set of numbers that are generated without a specific pattern or order and in a completely random form and become a table. To use the table of random numbers, we first preset the table to read the numbers (for example, up, down, left Or right) and then we consider numbers for the three groups in question. Consider the numbers 00-29 for intervention A, the numbers 30-59 for intervention B, and the numbers of 60-89 for group C. The researcher then touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups, thus making a random sequence.

Random allocation concealment refers to the method used to execute random sequences on study participants, in a way that prior to individual allocation, group allocated is not specified. In this study, in order to hide the random allocation, the method of opaque envelopes sealed with a random sequence is used. In this method, after making a random sequence based on the sample size of the research, a number of envelopes with aluminum wrapping (in order not to clarify the contents of the envelopes) are prepared and each of the random sequences created is recorded on a card and the card is sealed. Letters are placed in order. In order to preserve the random sequence, the numbering of the envelopes on the outer surface is done in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants to study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants did not know the type of drug and the time of drug injection and the time of acupuncture. The intern, as the lead researcher, has no knowledge of the type of drug. Nurses as health personnel do not know the type of medicine. Data Collectors do not know when the drugs were injected.

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

No. 17, Adjacent to the Passenger Terminal, Tehran Ave, Shahroud Town,

City

Shahroud

Province

Semnan

Postal code

3619943189

Approval date

2021-09-05, 1400/06/14

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1400.032

Health conditions studied

1

Description of health condition studied
Nausea and Vomiting after cesarean section
ICD-10 code
R10-R19
ICD-10 code description
Symptoms and signs involving the digestive system and abdomen

Primary outcomes

1

Description
Nausea and Vomiting
Timepoint
Nausea and Vomiting before intervention and 2, 24, 48 hours after surgery
Method of measurement
Comparative Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Injectable dexamethasone 8 mg dose is given to the patient about 30 minutes before the operation or immediately after induction of anesthesia. Dexamethasone produced by CHEMIST FACTORY Company. Dexamethasone is a corticosteroid drug and has anti-nausea and anti-emetic properties.
Category
Prevention

2

Description
Intervention group 2: Injectable ondansetron 4 mg injection is given intramuscularly or intravenously about 30 minutes before the operation or immediately after induction of anesthesia. (Ondansetron produced by CHEMIST FACTORY Company). It is a serotonergic receptor antagonist and has anti-nausea and vomiting properties.
Category
Prevention

3

Description
Control group: Acupuncture: In patients in the control group, we evaluate the effect of acupuncture. Stimulate the PC6 points in both hands after induction of anesthesia with a special needle for one time and for 15 seconds by rotating it clockwise and then remove the needle. The company is the importer of the product (Pars Medical Equipment Company).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam_Alanbia hospital
Full name of responsible person
Milad Johari
Street address
No. 17, Adjacent to the Passenger Terminal, Tehran Ave., Shahroud Town,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Behrouz Yahyaei
Street address
No. 17, Adjacent to the Passenger Terminal, Tehran Ave., Shahroud Town,
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Welfare Fund of Shahrood Azad University Medical School
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

Islamic Azad University

Full name of responsible person

Milad Johari

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

Milad Johari

Position

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Person responsible for updating data

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Name of organization / entity

Islamic Azad University

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"No more information"

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available