

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Study of the Effect of Ondansetron and Ginger on Nausea/Vomiting, Shivering and Headache after Spinal Anesthesia during and after Cesarean Section

Protocol summary

Study aim

Comparison of the Effects of Ondansetron and Ginger on Nausea/Vomiting, Shivering and Headache after Spinal Anesthesia during and after Cesarean Section

Design

Clinical trial with control group, with parallel, blinded, randomized phase 3 groups on 150 patients. Six random block method will be used for randomization.

Settings and conduct

The research community will be all pregnant mothers who visit the Fatemeh Hospital in Hamadan for cesarean section under spinal anesthesia. The participant, clinical caregiver and statistical analyzer will not be aware of the groups and the type of intervention. After coordination with the anesthesia team and the gynecological surgery team, the intervention will be performed. The condition of all participants will be the same including anesthesia, operating room temperature, coverage and type of serum received. If the desired consequences worsen, the medication will be prescribed according to the anesthesiologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age range of 20 to 40 years; 2. Physical status 1 or 2 in terms of ASA criteria; 3. Complete gestational age and singleton; 4. Cesarean candidate under spinal anesthesia. Exclusion criteria: 1. Unwilling to participate in the study; 2. History of mental disorders; 3. Body mass index greater than 35; 4. Meniere's disease; 5. Digestive Disease; 6. Frequent Dora holes and failed spinal anesthesia; 7. Allergy to ondansetron or ginger

Intervention groups

A) Ginger group: Taking one oral ginger capsule (1000 mg) with 30 ml of water one hour before receiving spinal anesthesia. B) Ondansetron group: Taking one ondansetron capsule (16 mg) with 30 ml of water one hour before receiving spinal anesthesia. C) Control

group: Taking a placebo capsule (containing rice flour) with 30 ml of water one hour before receiving spinal anesthesia.

Main outcome variables

Nausea/ Vomiting; Shivering; Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055172N1**

Registration date: **2022-07-03, 1401/04/12**

Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**

Update count: **0**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Sahar Alizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5612 8866

Email address

s.alizadeh@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of the Effect of Ondansetron and Ginger on Nausea/ Vomiting, Shivering and Headache after Spinal Anesthesia during and after Cesarean Section

Public title

The Effect of Ondansetron and Ginger on Nausea/ Vomiting, Shivering and Headache in Cesarean Section Patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 20 to 40 years Physical status 1 or 2 in terms of ASA criteria Complete gestational age and singleton Cesarean candidate under spinal anesthesia

Exclusion criteria:

Unwilling to participate in the study History of mental disorders Body mass index greater than 35 Meniere's disease Digestive Disease Frequent Dora holes and failed spinal anesthesia Allergy to Ondansetron or Ginger

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyzer

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

In the random block sampling method, different modes of three groups are written on six cards and each in an envelope is placed in the package. These envelopes are placed in a box, and the researcher does not know which research units will be placed in before selecting the card. Before exposure to the research units, the midwife picking up one of the envelopes from the box without awareness of the study and groups determines which group that will be included in the study, respectively.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, participants and clinical caregivers and data analyzer will be informed of the generality and method of implementation of the study, but will not be aware of the groups and the type of intervention received That is, the participant, clinical caregiver and

data analyzer will be unaware of where each participant is and what intervention has received.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Sciences

Street address

In front of Mardom's Park, Shahid Fahmideh Street, Pazhouhesh Square

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.UMSHA.REC.1401.316

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

Cesarean section

ICD-10 code

Z38.01

ICD-10 code description

Single liveborn infant, delivered by cesarean

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

Nausea based on visual analog scale score

Timepoint

During cesarean section (20 minutes after the start of surgery), when leaving the recovery (30 minutes after surgery is completed), 1, 2 and 4 hours after the surgery is completed

Method of measurement

Visual analog scale

2**Description**

Vomiting based on the vomiting frequency checklist

Timepoint

During cesarean section (20 minutes after the start of surgery), when leaving the recovery (30 minutes after surgery is completed), 1, 2 and 4 hours after the surgery is completed

Method of measurement

Vomiting frequency checklist

3

Description

Shivering based on the standard shivering scale score

Timepoint

During cesarean section (20 minutes after the start of surgery), when leaving the recovery (30 minutes after surgery is completed), 1, 2 and 4 hours after the surgery is completed

Method of measurement

Standard Shivering scale based on Crossley and Mahajan criteria

4

Description

Headache based on visual analog scale score

Timepoint

During cesarean section (20 minutes after the start of surgery), when leaving the recovery (30 minutes after surgery is completed), 1, 2 and 4 hours after the surgery is completed

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: This group is the ginger group, which will first be prepared as Zintoma oral capsules (250 mg) produced by Gol Daroo Pharmaceutical Company. Then, 1000 mg ginger capsule will be prepared in the pharmacology laboratory of Hamadan University of Medical Sciences under the supervision of a pharmacist. After coordination with the anesthesia team and the gynecological surgery team, the patient will be given a ginger capsule (1000 mg) with 30 ml of water one hour before receiving spinal anesthesia.

Category

Prevention

2

Description

Second Intervention group: This group is ondansetron group, which will first be prepared as ondansetron tablets (16 mg) produced by Exir Pharmaceutical Company. After coordination with the anesthesia team

and the gynecological surgery team, the patient will be given an ondansetron capsule (16 mg) with 30 ml of water one hour before receiving spinal anesthesia.

Category

Prevention

3

Description

Control group: Placebo capsule (containing rice flour) will be prepared in the pharmacology laboratory of Hamadan University of Medical Sciences under the supervision of a pharmacist. After coordination with the anesthesia team and gynecological surgery team, a placebo capsule (containing rice flour) with 30 ml of water one hour before The patient will be given spinal anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyeh hospital

Full name of responsible person

Sahar Alizade

Street address

Fatemieh Hospital, Pasdaran St.

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6517789971

Phone

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Email

h-fatemiyeh@umsha.ac.ir

Web page address

<https://fth.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

Street address

In front of Mardom's Park, Shahid Fahmideh Street, Pazhouhesh Square

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6517838736

Phone

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Email

Info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Alizade

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Surgical Technology

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Email

arielalizade@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Behzad Imani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Alizade

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Surgical Technology

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arielalizade@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All personal data is shared after unidentified individuals.

Includes demographic data and data on the severity of Nausea/Vomiting, Shivering, and Headache.

When the data will become available and for how long

The data is shared three months after the publication of the results.

To whom data/document is available

All researchers can apply for the data.

Under which criteria data/document could be used

The data is provided provided that they first have a clear purpose for using the data. Secondly, wherever this data

is to be used, the primary data source should be mentioned.

From where data/document is obtainable

Can use the the following e-mail address to receive the data. Behzadiman@yahoo.com

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

After sending the request to the e-mail address, the data will be sent as soon as possible.

Comments