Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Effectiveness of Ginger with Ondansetron on Nausea and Vomiting after Cesarean Section under Spinal Anesthesia with Fentanyl; a Randomized clinical Trial

Protocol summary

Study aim
Comparison of the Effectiveness of Ginger with Ondansetron on Nausea and Vomiting after Cesarean Section under Spinal Anesthesia with Fentany

Design
double-blind randomized clinical trial, phase 3 on 90 patients, web-based randomization software was used for randomization.

Settings and conduct
The present study will be performed on reducing nausea and vomiting in 90 patients aged 18-40 years who are candidates for cesarean section by spinal anesthesia in Bint Al-Huda Hospital of North Khorasan University of Medical Sciences. Patients are randomly assigned to three groups using a web-based system. Evaluation of nausea and vomiting by visual analog scale will be assessed at time intervals: recovery, 4, 8, 12 and 24 hours after surgery. To perform blinding, patients, surgeons, and individuals performing assessment work at different intervals will be blinded to the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients must be vigilant. Do not be the Absolute contraindications for spinal anesthesia. Do not have heart disease. Has not taken anti-nausea or corticosteroids in the 24 hours before surgery. Exclusion criteria: Do not be allergic to the drugs in the study.

Intervention groups
In the first group, patients receive two ginger capsules (each capsule containing one gram of ginger) orally. In the second group, patients receive two ondansetron tablets (each containing 4 mg of ondansetron). (Due to the blindness of the study, ondansetron tablets are placed inside the capsule cover in the same shape as other interventions) In the third group, patients receive two placebo capsules.

Main outcome variables
Intensity of nausea and Incidence of vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141001019359N13**
Registration date: **2022-04-10, 1401/01/21**
Registration timing: **prospective**

Last update: **2022-04-10, 1401/01/21**
Update count: **0**

Registration date
2022-04-10, 1401/01/21

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Ginger with Ondansetron on Nausea and Vomiting after Cesarean Section under Spinal Anesthesia with Fentanyl; a Randomized clinical Trial

Public title
Comparison of the Effectiveness of Ginger with Ondansetron on Nausea and Vomiting after Cesarean Section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients must be vigilant. Do not have the Absolute contraindications for spinal anesthesia. Do not have heart disease Has not taken anti-nausea or corticosteroids in the 24 hours before surgery.

Exclusion criteria:
Do not be allergic to the drugs in the study.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling in this study will be that first in order to enter the study patients will be in the form of non-random sampling of the type "available" and then divide them into three groups by randomly assigned blocking using a web-based system. Random blocking at www.randomization.com will be done in 15 blocks of 6. So that in each block, there are 2 people in the first group (A), two people in the second group (B) and two people in the third group (C). After a random sequence was identified in all blocks, cards were written by writing C, B, and A to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 90 in all blocks, respectively. They are numbered and these cards are placed in sealed non-transparent envelopes, respectively. Then, in order to hide the random allocation, when the patient visits, the opaque sealed envelope will be opened and then one by one, it will be determined for each sample of the relevant group.

Blinding (investigator's opinion)
Double blinded

Blinding description
None of the participants in the study will be aware of the randomization list, and in order to conceal the randomization process, the groups will be placed in closed envelopes in the reception area and will be assigned to the eligible individuals who enter the study. Also in all three groups; Patients receive the same intervention (receiving two capsules of the same shape one hour before the operation). Therefore, the study is double-blind so that patients and the outcome assessment specialist are unaware of the status of the three groups assigned to the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences

Street address
Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd

City
Bojnurd

Province
North Khorasan

Postal code
9416678894

Approval date
2022-03-15, 1400/12/24

Ethics committee reference number
IR.NKUMS.REC.1400.204

Health conditions studied

1

Description of health condition studied
nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Intensity of nausea and Incidence of vomiting

Timepoint
In recovery, 4, 8, 12 and 24 hours after surgery

Method of measurement
Scale for measuring nausea and vomiting

Secondary outcomes

1

Description
Drug side effects
Timepoint
During 24 hours after surgery
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
Intervention group 1: Patients receive two capsules of ginger (each capsule containing one gram of ginger) orally with 100 cc of city water one hour before surgery.
Category
Prevention

2

Description
Intervention group 2: Patients receive two ondansetron tablets (each containing 4 mg of ondansetron). (Due to the blindness of the study, ondansetron tablets are placed inside the capsule cover in the same shape as other interventions)
Category
Prevention

3

Description
Control group: Patients receive two placebo capsules (using the same dosage form) orally with 100 cc of city water one hour before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bint Al-Huda Hospital
Full name of responsible person
Dr. Shahin Mafi-nezhad
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Emam Ali hospital, Bojnurd, Iran
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Sponsors / Funding sources

1

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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
Bojnourd 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
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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