Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Compare adequate intraoperative fluid therapy with Ondansetron on the incidence and severity of nausea and vomiting

Protocol summary

Summary

The goal of this study is comparison adequate intraoperative fluid therapy with Ondansetron on the incidence and severity of nausea and vomiting after general surgery. In this clinical trial, 120 patients undergoing general were randomly divided into 3 groups. Group one: adequate intraoperative fluid therapy, Group two: pharmacological intervention with Ondansetron 0.06 mg per kg of body weight -and group three: without prophylactic intervention. Patients should be alert and have class 1 and class 2 of America Society of Anesthesiology (ASA). The incidence and severity of nausea and vomiting during the surgery, 2 and 6 hours after the surgery was assessed by self report scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080219359N6**
Registration date: **2016-09-03, 1395/06/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-03, 1395/06/13

Registrant information

Name
Hossein Zeraati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, North Khorasan University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare adequate intraoperative fluid therapy with Ondansetron on the incidence and severity of nausea and vomiting

Public title

Compare adequate intraoperative fluid therapy with Ondansetron on the incidence and severity of nausea and vomiting after general surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients should be alert; having class 1 and class 2 of America Society of Anesthesiology (ASA) score Exclusion criteria: the patients who weigh more than 90 kg; diabetics; with underlying gastrointestinal disease; those who had used anti-nausea and anti-vomiting drugs in pre-operative 24 hours before the surgery; those who were not fasting; those with middle ear disease; those who had more than 20% of baseline drop in blood pressure after spinal anesthesia; history of nausea and vomiting during the past 24 hours

Age

From **15 years** old to **60 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
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
Postal code
Approval date
2013-03-05, 1391/12/15
Ethics committee reference number
92P617

Health conditions studied

1

Description of health condition studied
Anesthesia
ICD-10 code
R10-119
ICD-10 code description
Symptoms and signs involving the digestive system and abdomen

Primary outcomes

1

Description
severity of nausea
Timepoint
During the surgery, 2 hour after the surgery, 6 hour after the surgery
Method of measurement
self-report scale

2

Description
Severity of vomiting
Timepoint
During the surgery, 2 hour after the surgery, 6 hour after the surgery
Method of measurement
self-report scale

Secondary outcomes

empty

Intervention groups

1

Description
The first Group: Under the prophylactic treatment liquid
Category
Other

2

Description
The second Group: pharmacological intervention with ondansetron 0.06 mg per kg of patient weight
Category
Treatment - Drugs

3

Description
The third group: without prophylactic interventions to prevent nausea and vomiting
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Hospital
Full name of responsible person
Javad Shahinfar
Street address
Emam Ali Hospital, Bojnurd, Iran.
City
Bojnurd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, North Khorasan University of Medical Sciences
Full name of responsible person
Alireza Golshan
Street address
Vice Chancellor for Research, North Khorasan University of Medical Sciences, Bojnurd, Iran
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Bojnurd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, North Khorasan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty