Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Compare the effect of ondansetron and Dexamethasone with metoclopramide and Dexamethasone in the control of nausea and vomiting after chemotherapy in cancer patients referred to Imam Hossein hospitals of Shahroud on 2017, a randomized double blind clinical trial

Protocol summary

Study aim
Compare the effect of ondansetron and Dexamethasone with metoclopramide and Dexamethasone in the control of nausea and vomiting after chemotherapy

Design
In this study, 86 patients who are referred to Imam Hossein Shahroud Hospital are referred for chemotherapy and admission to study. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct
This study was performed as a randomized clinical trial on patients referring to chemotherapy in Imam Hossein Hospital.The study is a double blind clinical trial in which the participants, the main researcher, the data collection authorities and those who evaluate the outcome are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: A definitive diagnosis of a cancer that needs chemotherapy There is no other systemic disease (such as obstructive bowel disease and gastroenteritis, central nervous system problems, and equilibrium problems) Have a previous history of chemotherapy at least three times Age range 15 to 65 years Fear and complain about severe and fairly intense nausea and vomiting in previous chemotherapy No use oral antinausea or injection medicines in the last 7 days Desire and satisfaction to enter the study Exclusion criteria: Use an anti-nausea and vomiting medicine for at least the past 7 days Dissatisfaction with this treatment Those who use drugs There is a severe allergic reaction to either of the two drugs, Endonestrone and Metoclopramide Dissatisfaction with cooperation and participation in the project

Intervention groups
Intervention group: Ondonestrone 0 / 1mg / kg with 2 cc normal saline plus 8 mg dexamethasone intravenously Control group: Metoclopramide 0.15 mg / kg plus 8 mg dexamethasone intravenously

Main outcome variables
Severity of pain; nausea and vomiting; complication after treatment of two drugs; severe nausea after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170902036032N1**
Registration date: **2018-02-25, 1396/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-25, 1396/12/06**
Update count: **0**

Registration date
2018-02-25, 1396/12/06

Registrant information

Name
mehrshad mousapour

Name of organization / entity
medical student in shahroud medical sience university

Country
Iran (Islamic Republic of)

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+98 990 173 6066

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the effect of ondansetron and Dexamethasone with metoclopramide and Dexamethasone in the control of nausea and vomiting after chemotherapy in cancer patients referred to Imam Hossein hospitals of Shahroud on 2017, a randomized double blind clinical trial

Public title
Compare the effect of ondansetron and Dexamethasone with metoclopramide and Dexamethasone in the control of nausea and vomiting after chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
A definitive diagnosis of a cancer that needs chemotherapy There is no other systemic disease (such as obstructive bowel disease and gastroenteritis, central nervous system problems, and equilibrium problems) Have a previous history of chemotherapy at least three times Age range 15 to 65 years Fear and complain about severe and fairly intense nausea and vomiting in previous chemotherapy No use oral antinausea or injection medicines in the last 7 days Desire and satisfaction to enter the study
Exclusion criteria:
Use an anti-nausea and vomiting medicine for at least the past 7 days Dissatisfaction with this treatment Those who use drugs There is a severe allergic reaction to either of the two drugs, Endonestrone and Metoclopramide Dissatisfaction with cooperation and participation in the project
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple, Individual randomization unit Using random quadrants blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a double blind clinical trial in which the participants, the main researcher, the data collection authorities and those who evaluate the outcome
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahroud University of Medical Sciences
Street address
shahroud University of Medical Sciences and Health Services,Hafte-Tir Square,Shahroud
City
Shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۷
Approval date
2016-11-09, 1395/08/19
Ethics committee reference number
IR.SHMU.REC.1395.124

Health conditions studied

1

Description of health condition studied
Under chemotherapy
ICD-10 code
Z51.11
ICD-10 code description
Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description
Severity of pain
Timepoint
After treatment
Method of measurement
Visual Scale

2

Description

nausea and vomiting

Timepoint

After treatment

Method of measurement

Visual Scale

3

Description

complication after treatment of two drugs

Timepoint

After treatment

Method of measurement

Visual Scale

4

Description

severe nausea after treatment

Timepoint

After treatment

Method of measurement

Visual Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ondonestrone 0 / 1mg / kg with 2 cc normal saline plus 8 mg dexamethasone intravenously

Category

Treatment - Drugs

2

Description

Control group: Metoclopramide 0.15 mg / kg plus 8 mg dexamethasone intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Shahrood Hospital Medical Center

Full name of responsible person

Mehrshad Mousapour

Street address

Lane 28-meter Ayatollah Tohidi ,Imam Street. Shahrood City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Shahroud University of Medical Sciences and Health Services,Hafte-Tir Square,Shahroud

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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

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Mehrshad Mousapour

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

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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