

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 anti-nausea 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 science university

Country

Iran (Islamic Republic of)

Phone

+98 990 173 6066

Email address

mousapour@shmu.ac.ir

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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Postal code

1448813879
Phone
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Email
mehrshadmousapour@gmail.com

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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Postal code
۳۶۱۴۷-۷۳۹۴۷
Phone
+98 23 3239 5054
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emamian@shmu.ac.ir
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 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