

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A Comparison of metoclopramide with Ondansetron for Treating Nausea in Adult Patient

Protocol summary

Study aim

Comparison of Metoclopramide and Ondansetron in controlling nausea in adult patients

Design

Triple controlled parallel groups ,double blind, clinical trials with frequent measurements

Settings and conduct

Patients referred to Emergency of Imam Khomeini Hospital with a complaint of nausea are assigned randomly to one of three treatment groups. These patients will not know what group they are in. The pharmacist, without the knowledge of the investigator, will encode the medications. So, the investigator, doctor and nurse will also be unaware of the name of the drug they received

Participants/Inclusion and exclusion criteria

Participants Inclusion criteria: over 18 years of age, conscious, need to get an anti-nausea medicine as directed by the doctor, the severity of nausea greater than 40 mm in a ruler scale such as the Visual Analog Scale (VMS) analogue scale (100 mm). Participants exclusion criteria: unstable hemodynamics (systolic blood pressure less than 90mmHg), history of allergies to any of the drugs studied, pregnancy, receiving an anti-nausea medicine in the last 24 hours, any disability (physical and mental) and patient's unwillingness.

Intervention groups

The intervention groups consisted of three groups of Ondansetron therapy, Metoclopramide and Placebo, normal saline

Main outcome variables

Severity of nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180717040509N1**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **retrospective**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Mahboubbeh Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3321 7982

Email address

m.eslami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-09-21, 1395/06/31

Actual recruitment start date

2016-01-21, 1394/11/01

Actual recruitment end date

2016-09-21, 1395/06/31

Trial completion date

empty

Scientific title

A Comparison of metoclopramide with Ondansetron for Treating Nausea in Adult Patient

Public title

Comparison of metoclopramide with Ondansetron for Treating Nausea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with Nausea sign

Exclusion criteria:

Age under 18 years Pregnant patients Patients with mental and physical disabilities Patients with a history of allergy to study drugs Patients with systolic blood pressure less than 90mmHg Receive an anti-nausea medicine in the last 24 hours

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization, block Random unit: Individual
Randomization Tool: Table of Random Numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are assigned Simple randomization to one of the three treatment groups by department staff. So, patients will not know what group they are in. The pharmacist of the study, without the knowledge of the investigator, doctor and nurse will code the drugs (codes A, B, C). In this way, the investigator, doctor and nurse will also be unaware of the name of the drug they received

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mazandaran university of medical science

Street address

Moallem Square

City

Sari

Province

Mazandaran

Postal code

4817844818

Approval date

2018-01-09, 1396/10/19

Ethics committee reference number

IR.MAZUMS.REC.1395.1720

Health conditions studied

1

Description of health condition studied

Nause

ICD-10 code

R11.0

ICD-10 code description

Nausea

Primary outcomes

1

Description

Severity of nausea based on Visual Analog Scale

Timepoint

At the beginning of the study (before the injection) and 30 minutes after the injection of the drug

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Ondansetron 4mg / 2ml, manufactured by Tehran Chemistry Co., is prepared in 2ml syringes. Drug injections will be given by a nurse with the help of angiogenesis in the peripheral blood vessels of the patient.

Category

Treatment - Drugs

2

Description

Second Intervention group: Methoclopramide 10mg / 2ml drug manufactured by Tehran Chemistry Co. is prepared in 2 ml syringes. Drug injections will be given by a nurse with the help of angiogenesis in the peripheral blood vessels of the patient.

Category

Treatment - Drugs

3

Description

Control group: The normal saline of the placebo is prepared in 2 ml syringes. The injection will be done by a nurse with the help of angiogenesis located in the peripheral vascular of the patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Fatemeh Jahaniyan

Street address

Emam Khomeini Haospital, Amir Mazandarani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Jahaniyan

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable