

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Comparison of Granisetron and Ondansetron on nausea and vomiting in adult patients referred to the emergency department

Protocol summary

Study aim

Comparison of the effect of Ondansetron and Granisetron on adult patients referred to the emergency department with nausea and vomiting

Design

Phase 3 clinical trial, with parallel, double-blind, randomized groups

Settings and conduct

Patients Referred to Emergency Department of Imam Khomeini Hospital and Golestan Hospital in Ahvaz with Complaints of nausea and vomiting divide into two equal groups and one group received consciously injected 4mg intravenous Ondansetron and the other group received 1 mg intravenous Granisetron and at times 15, 30 ,45,60,75,90 minutes the VAS method is queried and the results recorded. Subjects were randomly divided into two groups according to the randomized block design method and the study was conducted as a double blind study in this study, the patient and the questioner will be blind.

Participants/Inclusion and exclusion criteria

In this study, all patients with nausea and vomiting and especially patients with nausea and vomiting with vertigo or with gastroenteritis symptoms are admitted to our Emergency Department of Imam Khomeini and Golestan Hospital in Ahvaz. Accompanied by symptoms such as headaches, lateralized symptoms, Unstable vital signs, patients with no consent to attend or continue treatment , patients with chest pain or ECG changes, patients with Rise ICP symptoms or patients who have received serotonin in the last few days (Such as Fluoxetine, Doxepin, Isomerboxazide, Amitriptyline, etc.) or drugs that stimulate hepatic cytochrome p450 or inhibitors of liver enzymes have used and patients who have consumed grapefruit in the last 24 hours are excluded from our study.

Intervention groups

Patients divide into two equal groups and one group received consciously injected 4mg intravenous

Ondansetron and the other group received 1 mg intravenous Granisetron.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191007045013N1**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Akram Shiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3293 5927

Email address

akramshiri1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Granisetron and Ondansetron on nausea and vomiting in adult patients referred to the emergency department

Public title

Comparison of Granisetron and Ondansetron on nausea and vomiting in adult patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Nausea and vomiting in adult patients

Exclusion criteria:

Patients with symptoms such as headaches, lateralized symptoms, and unstable vital signs. Patients who have chest pain or ECG changes. Patients with symptoms of Rise ICP. Patients who have been taking serotonin (eg, fluoxetine, doxepin, isomerboxazide, amitriptyline, etc.) in the past few days. Patients who have used hepatic cytochrome P450 enzyme stimulating drugs or liver enzyme inhibitors in recent days. Patients who have consumed grapefruit in the past 24 hours Patient does not consent to attend or continue treatment.

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient will randomly divide into two groups according to the method of quadratic random block permutation, after sorting patients by computer, the number of each patient and the drug combination used will be identified and the drugs packaged in packages, only the number on each envelope is that the executor and the nurse are unaware of its contents and the list of medicines is only available to the researcher

Blinding (investigator's opinion)

Double blinded

Blinding description

In this randomized controlled trial, patients are given one of two drugs, Granisetron or Ondansetron, which has no information about the type of drug used by the patient, the injector, and the person examining the effects of the drug. (Patient informed consent to participate in this study and randomized injection of either drug)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2019-08-04, 1398/05/13

Ethics committee reference number

IR.AJUMS.REC.1398.352

Health conditions studied**1****Description of health condition studied**

Nausea and vomiting in patients admitted to the emergency department

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes**1****Description**

Nausea

Timepoint

15minute, 30minute, 45minute, 60minute, 75 minute, 90minute after to take Granisetron or Ondansetron

Method of measurement

Using a visual analogue scaling method where the patient signs a nausea rate on a line measuring 10 cm in length from zero to ten

2**Description**

Vomiting

Timepoint

15,30,45,60,75,90minute after to take Granisetron or Ondansetron

Method of measurement

Count the number of vomiting

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group was injected with a conscious consent of 4 mg intravenous Ondansetron(Tehran chemistry company product) in single dose and nausea and vomiting are measure 15,30,45,60,75,90 minutes after to take Ondansetron by visual analogue scale method and questionnaire .

Category

Treatment - Drugs

2

Description

The second intervention group was injected with a conscious consent of 1 mg intravenous Granisetron(Aboureihan company product) in single dose and nausea and vomiting are measure 15,30,45,60,75,90 minutes after to take Granisetron by visual analogue scale method and questionnaire .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeyni hospital

Full name of responsible person

Alivefagh Nematollahi

Street address

Emergency medicine ,Imam Khomeyni hospital ,Azadegan Street ,Ahvaz

City

Ahvaze

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2922

Email

Alivefagh@yahoo.com

2

Recruitment center

Name of recruitment center

Golestan

Full name of responsible person

Alivefagh Nematollahi

Street address

Emergency medicine,Golestan hospital,Cui Golestan,Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

411366718596

Phone

+98 61 3374 3001

Email

Alivefagh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad badavy

Street address

Faculty of medicine, Ahvaz Jundishapur university of medical sciences, Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 3815

Email

itc@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Alivefagh Nematollahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Emergency Medicine ,Imam Khomeini training center,Azadegan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 9166

Email

alivefagh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Alivefagh Nematolahy

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Emergency Medicine, Imam Khomeini Training Center, Azadegan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 9166

Email

Alivefagh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Akram Shiri

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

Emergency Medicine

Street address

Second floor,NO.205,Panahsazan apartment, Cafi Ave between Adham Ave and Kramikharat Ave, Naderi, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6196654716

Phone

+98 61 3445 3012

Email

Akramshiri1373@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Patient information including nausea and vomiting and associated symptoms that the patient has been referred to, how to use the medication and its effects on patients recorded through the questionnaire, and the patient's informed consent to participate in the study. But the names of study participants are not shared for patient privacy.

When the data will become available and for how long

The start of the access period after the end of the job is the result of the confirmation.

To whom data/document is available

It will be accessible to everyone.

Under which criteria data/document could be used

Use nausea and vomiting or granisetron or ondansetron or emergency keywords to access this study.

From where data/document is obtainable

Email your requests to alivefagh@yahoo.com.

What processes are involved for a request to access data/document

Request email to study person.

Comments