Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of Granisetron and Ondansetrone 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 vomitung 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, Uunstable 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 sertonin 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
Nausa 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)

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+98 61 3293 5927

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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 Ondansetrone on nausea and vomiting in adult patients referred to the emergency department

Public title
Comparison of Granisetron and Ondansetrone 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 sertonin (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
Khouzestan
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

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Khouzestan

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2

Recruitment center

Name of recruitment center

Golestan

Full name of responsible person

Alivefagh Nematollahi

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Emergency medicine,Golestan hospital,Cui Golestan,Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad badavy

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Intern

Latest degree
A Level or less

Other areas of specialty/work
Emergency Medicine

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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