

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The comparison between Olanzapine- Aprepitant- Granisetron effects on chemotherapeutic drug induced nausea and vomiting in patients

Protocol summary

Study aim

Determine and comparison between Olanzapine- Aprepitant- Granisetron effects on chemotherapeutic drug induced nausea and vomiting in patients of Ali Ibn Abitaleb Hospital

Design

This is a Phase 3 clinical trial with parallel, blind and randomized groups. First, qualified samples enter in Convenient non-randomly method, then they'll be allocated into one of three groups of Olanzapine- Aprepitant- Granisetron using permuted block randomization method.

Settings and conduct

Study population included patients in Ali Ibn Abitaleb Hospital (Zahedan) undergoing chemotherapy. After grouping, groups are randomly named 1, 2 and 3, and corresponding assistant who records patients clinical information, as well as patients, will be blinded for drug names.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent, Receiving chemotherapy regimens with moderate-high nausea and vomiting, Serum Creatinine 2 or less, Not having another cause for nausea and vomiting like stomach cancer. exclusion criteria: Having uncontrollable nausea and vomiting, Having allergies or other medications side effects, Pregnant and lactating women, Use other interventions or confusing drugs (Quinolones, other underlying conditions ,etc.), Having nausea and vomiting 24 hours before treatment.

Intervention groups

Group1: 5 mg Oral Olanzapine daily in 3 days Group2: Kytril tablet 2 mg+ 125 mg oral Aprepitant on day one, 80 mg in second and third day Group3: 1 g Granisetron ampoules daily in 3 days

Main outcome variables

Nausea and vomiting of chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190217042735N1**

Registration date: **2019-07-27, 1398/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Farnoush Tajbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5744

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-09, 1398/04/18

Expected recruitment end date

2019-10-10, 1398/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between Olanzapine- Aprepitant- Granisetron effects on chemotherapeutic drug induced nausea and vomiting in patients

Public title

Comparison between Olanzapine- Aprepitant- Granisetron on nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Receiving chemotherapy regimens with moderate and high nausea and vomiting Serum Creatinine 2 or less AST and ALT less than 3 times of normal upper limit Absolute Neutrophil counts of more than 1500 cubic millimeters Not having another cause for nausea and vomiting, such as brain tumors and stomach cancer

Exclusion criteria:

Having nausea and vomiting too much and uncontrollable Having allergies or showing other side effects of medications Pregnant and lactating women Having chronic illnesses such as: severe heart failure, uncontrolled diabetes, cardiac arrhythmia and cardiac infarction over the past 6 months Use of other interventions or confusing drugs (Quinolones, abdominal radiotherapy, other underlying conditions, etc.) Treatment with other antipsychotic drugs (Risperidone, Quetiapine, Clozapine, Phenothiazine) 30 days before entering the study Having known problem in the CNS (cerebral metastasis or seizure) or cognitive impairment Having nausea and vomiting 24 hours before treatment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be randomized with the help of permutation blocks. At first, the eligible samples will enter the study in easily or accessible method, then using randomized block method, they'll enter in one of the three study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

We will explain to patients that according to the use of double blind technique, the type of drug used and the group which they are placed will not be informed to them, and if they do not accept, they will not be included in the study. After treatment, patients will be monitored for nausea and vomiting on the first day and 48 to 72 hours after chemotherapy and their clinical data will be

recorded. During the study and after grouping, the groups are randomly named 1, 2, and 3, and the corresponding assistant who records the patients' clinical information, as well as the patients, will not be involved in the medications used by the name of the drugs. The main researcher will not be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Medical campus, Dr Hesabi sq.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

ir.zaums.rec.1397.053

Health conditions studied

1

Description of health condition studied

Nausea and Vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

First day and 48 to 72 hours after chemotherapy

Method of measurement

The patients will be monitored for nausea and vomiting on the first day and 48 to 72 hours after chemotherapy, and their clinical data will be recorded by the information form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Olanzapine: 5mg Oral Olanzapine daily in 3 days

Category

Treatment - Drugs

2

Description

Intervention group: Aprepitant: Kytril tablet 2mg+125mg oral Aprepitant on day one,80mg in second and third day

Category

Treatment - Drugs

3

Description

Intervention group: Granisetron: 1g Granisetron ampoules daily in 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn abitalib Hospital of Zahedan

Full name of responsible person

Mohammad Kazem Momeni

Street address

Ali Ibn Abitalib Hospital, Salamat Blvd., Khalijefars Highway

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Drkazemmomeni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Medical campus, Dr Hesabi sq.

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Farnoush Tajbakhsh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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