Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

f.tajbakhsh@zaums.ac.ir

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
City
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Sistan-va-Balouchestan
Postal code
9816743111
Phone
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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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Email
taheri@zaums.ac.ir
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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Person responsible for scientific inquiries

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Full name of responsible person

Farnoush Tajbakhsh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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