Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison between the effect of Triplet Aprepitant/Dexamethasone/Ondansetron vs. doublet Dexamethasone/Ondansetron for prevention of moderately emetogenic chemotherapy: placebo-controlled double blind, randomised clinical trial of efficacy

Protocol summary

Study aim
To evaluate efficacy of adding Aprepitant to doublet dexamethasone/Ondansetron for prevention of moderately emetogenic chemotherapy regimens' emesis

Design
placebo-controlled double blind, randomised clinical trial of efficacy

Settings and conduct
160 cancer patients under moderate emetogenic chemotherapy regimen, in Imam Hussein Hospital between December 2018 and march 2019 were enrolled. Patients were treated with triple antiemetic therapy comprising oral administration of 125 mg Aprepitant and intravenous injection of 12 mg Dexamethasone, and 8mg Ondansetron on day 1, followed by 80 mg Aprepitant on days 2 and 3. The control group received the same regimen without Aprepitant.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: aged between 18 - 70 years, Karnofsky index of 50% or more; Women at reproductive ages should had received an appropriate contraceptive ; Exclusion Criteria: causes of nausea or vomiting unrelated to the chemotherapy; uremia or electrolyte disturbance; active infection; uncontrolled seizure; candidate for radiation therapy of brain or upper abdomen in less than a week; received an anti emetic 24 h before ;lab studies : wbc<3000/mm3 , anc<1500/mm3 , plt<100000 mm3, ALT & AST>2.5 * upper limit of normal, Bill & Cr > 1.5* upper limit of normal ; opium addicted; poor compliance ; received corticosteroids for more than 3 months and more than 50 mg prednisone daily; Carlson’s comorbidity scale of 3 or more.

Intervention groups
Patients were treated with triple antiemetic therapy comprising oral administration of 125 mg Apprepitant ,intravenous injection of 12 mg dexamethasone, and 8mg ondansetron on day 1, followed by 80 mg Abitant on days 2 and 3. The control group received the same regimen without Aprepitant

Main outcome variables
nausea and vomiting; complete response (no vomiting, no need of rescue medication)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191103045317N1**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **retrospective**

Last update: **2019-11-30, 1398/09/09**
Update count: **0**

Registration date
2019-11-30, 1398/09/09

Registrant information

Name
Mania Rajabzadeh kheradmardi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7754 3634

Email address
mania_008@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-21, 1397/09/30
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
2018-12-21, 1397/09/30
Actual recruitment end date
2019-03-20, 1397/12/29
Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison between the effect of Triplet Aprepitant/Dexamethasone/Ondansetron vs. doublet Dexamethasone/Ondansetron for prevention of moderately emetogenic chemotherapy: placebo-controlled double blind, randomised clinical trial of efficacy

Public title
efficacy of adding Aprepitant into antiemesis prophylactic regimen in nausea and vomiting of moderate emetogenic regimen
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients receiving moderate emetogenic chemotherapy regimens,formed the study cohort. Eligible patients were adults (aged between 18 - 70 years) with a karnofsky index of 50% or more). Women at reproductive ages should had undertaken an appropriate contraceptive method
Exclusion criteria:
causes of nausea or vomiting unrelated to the chemotherapy (e.g., gastrointestinal obstruction, massive ascites, widespread brain metastases, history of motion sickness or vestibular dysfunction, uremia or electrolyte disturbance) active infection uncontrolled seizure candidate for radiation therapy of brain or upper abdomen in less than a week an emetic episode 24 h before initiation of chemotherapy complications that prohibited Dexamethasone use one of the followings observed in their lab studies : wbc<3000/mm3 , anc<1500/m m3 , plt<100000 mm3, ALT & AST>2.5 * upper limit of normal,Bill & Cr > 1.5* upper limit of normal opium addicted poor compliance receiving corticosteroids for more than 3 months and more than 50 mg Prednisone daily; Carlson’s comorbidity scale of 3 or more Any drugs with antiemetic efficacy other than the study drugs wouldn’t been allowed before the study started, and were recorded on.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization sequences was created using Stata10 statistical software ; using random block sizes of 4. participants stratified by a center of 1:1 allocation ,randomly assigned to either the case (Aprepitant) or the control (placebo) group; with equal proportion of male and female patients in each group to eliminate the confounding effect of sex.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and medical treatment team were unaware of being in case or control groups, as the drugs were coded by the pharmaceutical company, and they were decoded after the time the data were collected and analyzed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Jorjani center of radiotherapy-oncology, Imam Hussein Hospital, Madani Ave., Imam Ali Blvd,.Nezan Abad Town,
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2017-08-22, 1396/05/31
Ethics committee reference number
67m

Health conditions studied

1

Description of health condition studied

nausea and vomiting

ICD-10 code

R11.2

ICD-10 code description

Nausea with vomiting, unspecified

2

Description of health condition studied

adverse reaction

ICD-10 code

T45

ICD-10 code description

Poisoning by, adverse effect of and underdosing of primarily systemic and hematological agents, not elsewhere classified

Primary outcomes

1

Description

Proportion of patients experiencing nausea and vomiting with MSKCC questionnaire

Timepoint

day 1 and 5 of chemotherapy

Method of measurement

MSKCC nausea and vomiting questionnaire

Secondary outcomes

1

Description

complete response

Timepoint

day 1 and day 5 of chemotherapy

Method of measurement

MSKCC nausea and vomiting questionnaire

2

Description

complete control

Timepoint

day 1 and day 5 of chemotherapy

Method of measurement

MSKCC nausea and vomiting questionnaire

3

Description

overall response

Timepoint

day 1 and day 5 of chemotherapy

Method of measurement

MSKCC nausea and vomiting questionnaire

4

Description

resistance to treatment

Timepoint

day 1 and day 5 of chemotherapy

Method of measurement

MASCC nausea and vomiting questionnaire

Intervention groups

1

Description

Intervention group: Patients were treated with triple antiemetic therapy comprising oral administration of 125 mg Aprepitant and intravenous injection of 12 mg Dexamethasone, and 8mg Ondansetron on day 1, followed by 80 mg Aprepitant on days 2 and 3

Category

Prevention

2

Description

Control group: received intravenous injection of 12 mg Dexamethasone, and 8mg Ondansetron on day 1, and placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein hospital

Full name of responsible person

Mania Rajabzadeh Kheradmardu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Rezghi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Abidi Pharmaceutical iran

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mania Rajabzadeh Kheradmardi
Position
resident of radiation oncology
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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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

Patients' ID, sex, case or control, nausea, vomiting, complete control, complete response , overall response, resistance to treatment,

When the data will become available and for how long

3 months after results publication

To whom data/document is available

researchers of academic and scientific centers

Under which criteria data/document could be used

researching utilization of similar studies

From where data/document is obtainable

contributing author: mania_008@yahoo.com

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

An applying email from the named accepted centers

Comments