

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 Aprepitant ,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

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 have 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/mm³ , 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
Street address
Shahid madani Ave., Nezam Abad Town
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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
Street address
Jorjani Center of Radiation-Oncology, Imam Hussein Hospital, Shahid madani Ave., Nezam Abad Town,

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zarghi@sbmu.ac.ir

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 scientific inquiries

Contact

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Full name of responsible person
Morteza Tabatabaefar

Position
Associate professor

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Person responsible for updating data

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Associate professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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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