# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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

**Street address**

Shahid madani Ave., Nezam Abad Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7754 3634

**Email**

mania_008@yahoo.com

**Web page address**

## 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,

**City**
Tehran
**Province**
Tehran
**Postal code**
1617763141
**Phone**
+98 21 7754 3634
**Email**
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
**Street address**
Jorjani center of radiation oncology, Imam Husein Hospital, Shahid Madani Ave., Nezam Abad Town
**City**
Tehran
**Province**
Tehran
**Postal code**
1617763141
**Phone**
00982÷77543634
**Email**
mania_008@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Morteza Tabatabaeefar
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Radiotherapy
**Street address**
Imam Hussein Hospital, Shahid madani Ave., Nezam Abad Town
**City**
Tehran
**Province**
Tehran
**Postal code**
1617763141
**Phone**
+98 21 7754 3634
**Email**
tabatabaeefar@hotmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Ali Yaghoubi jouybari
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Radiotherapy
**Street address**
Imam Hussein Hospital, Shahid Madani Ave., Nezam Abad Town
**City**
Tehran
**Province**
Tehran
**Postal code**
1617763141
**Phone**
+98 21 7754 3634
**Email**
dryaghobi@sbmu.ac.ir

## 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**