Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of increase in duration of Aprepitant consumption from 3 to 6 days on the prevention of nausea and vomiting in women receiving combination of Anthracycline/Cyclophosphamide chemotherapy: A randomized, crossover, clinical trial

Protocol summary

Summary

1) Objective: Better control of chemotherapy induced nausea and vomiting by increasing the duration of Aprepitant consumption in women with breast cancer who receive AC (Anthracycline/Cyclophosphatase) regimen chemotherapy. 2) Design: Randomized, crossover, controlled clinical trial, designed to evaluate the effect of increase in duration of Aprepitant usage from 3 days to 6 days on prevention of nausea and vomiting in women receiving combination of Anthracycline/Cyclophosphatase chemotherapy. 3) Setting and conduct: This trial is conducted in cancer referral university hos¬pital in Isfahan (Iran's third largest city, located in the center of Iran), Iran 4) Participant including major eligibility criteria: patients who are under 50 years of age, diagnosed with breast cancer and scheduled to receive 4 courses AC regimens are included in the study. The following general exclusion criteria are considered: gastritis; diabetes and brain tumor. 5) Intervention: Fifty patients with breast cancer will enroll in this study through convenience sampling method. They will randomize into two groups. According to the design of the study, group 1 will receive treatment A (3 days regimen) in the first course of chemotherapy and treatment B (6 days regimen) in the second course; group 2 will receive treatment B follow by treatment A. 6) Main outcome measures criteria: Main outcome is complete response (CR) that is defined as no nausea and no episode of vomiting during the study period. For nausea and vomiting assessment, we used Eastern Cooperative Oncology Group (ECOG) COMMON TOXICITY CRITERIA questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040121574N1**
Registration date: **2015-06-20, 1394/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-20, 1394/03/30

Registrant information

Name
Negah Chabi Ahvazi
Name of organization / entity
Esfahan university of medical science
Country
Iran (Islamic Republic of)
Phone
+98 31 4521 3496
Email address
dr.n.ahvazi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of increase in duration of Aprepitant consumption from 3 to 6 days on the prevention of nausea and vomiting in women receiving combination of Anthracycline/Cyclophosphamide chemotherapy: A randomized, crossover, clinical trial

Public title
Investigation of the effect of increasing days of abitant capsul use in control of chemotherapy induced nausea and vomiting with AC regimen in women with breast cancer

Purpose
Prevention

Inclusion/Exclusion criteria
General inclusion criteria: Less than 50 years of age, diagnosed with breast cancer and scheduled to receive 4 courses Anthracycline/Cyclophosphamide (AC) regimens.
General exclusion criteria: previous history of gastritis, diabetes and brain tumor.

Age
From **24 years** old to **50 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **49**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Efahan university of medical sciences

Street address
Isfahan university of medical sciences,Hezar Jerib street, Esfahan

City
Esfahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
393449

Health conditions studied

1

Description of health condition studied
Chemotherapy induced nausia and vomitting

ICD-10 code
T45.1

ICD-10 code description
Antineoplastic and immunosuppressive drugs, Poisoning by primarily systemic and haematological agents, not elsewhere classifiedAntineoplastic and immunosuppressive drugs

2

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Complete response

Timepoint
6 days after begining of intervention

Method of measurement
Questionnaire based on ECOG criteria

Secondary outcomes

empty

Intervention groups

1

Description
6 days consumption of Abitant capsul

Category
Treatment - Drugs

2

Description
3 days consumption of Abitant capsul

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyedoshohada Hosspital
Full name of responsible person
Dr.Simin Hemmati
Street address
Seyedoshohada Hosspital, Khayam street, Esfahan
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Esfahan university of medical science
Full name of responsible person
Dr.Simin Hemmati
Street address
Isfahan university of medical sciences,Hezar Jerib street, Esfahan
City
Esfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Esfahan university of medical science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan university of medical science
Full name of responsible person
Dr.Simin Hemmati
Position
Assistant professor
Other areas of specialty/work
Street address
Radiotherapy unit, Isfahan university of medical sciences,Hezar Jerib street, Esfahan
City
Esfahan
Postal code
Phone
+98 31 3793 2335
Fax
Email
hemati@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan university of medical science
Full name of responsible person
Dr.Simin Hemmati
Position
Assistant professor
Other areas of specialty/work
Street address
Radiotherapy unit, Isfahan university of medical sciences,Hezar Jerib street, Esfahan
City
Esfahan
Postal code
Phone
+98 31 3793 2335
Fax
Email
hamati@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Esfahan university of medical science
Full name of responsible person
Dr.Simin Hemmati
Position
Assistant professor
Other areas of specialty/work
Street address
Radiotherapy unit, Isfahan university of medical sciences,Hezar Jerib street, Esfahan
City
Esfahan
Postal code
Phone
00
Fax
Email
hemati@med.mui.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty