

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigating the anti-emetic effect of *Rheum ribes L.* aqueous extract on breast cancer patients receiving ACT chemotherapy

#### Protocol summary

##### Study aim

Evaluate the effect of aqueous extract of *Rheum ribes L.* on the onset of ACT-induced nausea in patients with breast cancer

##### Design

Double-blind clinical trail

##### Settings and conduct

Yazd, Shah vali hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with breast cancer, aged range of 20-80 years, ACT chemotherapy regimen, complete patient satisfaction, and the first or second course of chemotherapy exclusion criteria: patients with other cancer history, history of receiving chemotherapy, history of seizure and use of anticonvulsant drugs, nausea and vomiting degree 2 or 3 within 24 hours prior to chemotherapy, persistent, moderate or severe nausea, Hepatitis or gastrointestinal obstruction and metastasis

##### Intervention groups

The intervention group receives aqueous extract of *Rheum ribes L.* with anti-emetic medicines such as aprepitant and ondansetron. the control group receives placebo with anti-emetic medicines such as aprepitant and ondansetron.

##### Main outcome variables

Severity of nausea, duration of nausea, frequency of vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140817018828N6**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **retrospective**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

##### Registration date

2018-06-27, 1397/04/06

##### Registrant information

###### Name

Alimohammad Ranjbar

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3820 3419

###### Email address

amranjbar@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2017-06-21, 1396/03/31

##### Actual recruitment start date

2016-08-29, 1395/06/08

##### Actual recruitment end date

2017-07-21, 1396/04/30

##### Trial completion date

empty

##### Scientific title

Investigating the anti-emetic effect of *Rheum ribes L.* aqueous extract on breast cancer patients receiving ACT chemotherapy

##### Public title

Investigating the anti-emetic effect of *Rheum ribes L.*

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with breast cancer Adriamycin, Cytoxan, Taxol (ACT) chemotherapy regimen The first or second course of chemotherapy Patient's satisfaction

**Exclusion criteria:**

Patients with other cancer history History of receiving chemotherapy History of seizure and use of anti-convulsant drugs Nausea and vomiting degree 2 or 3 within 24 hours prior to chemotherapy Persistent, moderate or severe nausea Hepatitis or gastrointestinal obstruction and metastasis

**Age**

From **20 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **56**

Actual sample size reached: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The numerical codes were drawn on the label of the extract and placebo glass based on the random numbers table prepared using the random block method

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Extract and placebo was coded by a third person and patients; Statiscian; The author responsible for gathering data didnt aware of the content of the glasses, and their code was secretly kept until the end of the project.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences

**Street address**

Bahonar square, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8917693571

**Approval date**

2016-07-16, 1395/04/26

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1395.68

**Health conditions studied****1****Description of health condition studied**

Breast cancer

**ICD-10 code**

C50-C50

**ICD-10 code description**

Malignant neoplasm of breast

**Primary outcomes****1****Description**

Severity of nausea

**Timepoint**

8 days after receiving chemotherapy

**Method of measurement**

National Chemotherapy Institute (NCI) table of nausea grade

**Secondary outcomes****1****Description**

Duration of nausea

**Timepoint**

8 days after chemotherapy

**Method of measurement**

How many days have nausea

**2****Description**

Frequency of vomiting

**Timepoint**

8 days after chemotherapy

**Method of measurement**

National Chemotherapy Institute (NCI) table of vomiting grade

**Intervention groups****1****Description**

Intervention group: aqueous extract of Rheum ribes L. , in 7 days, 5cc every day

**Category**

Treatment - Drugs

2

**Description**

Control group: placebo, in 7 days, 5cc every day

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Yazd, Shah vali hospital

**Full name of responsible person**

Seyede Negin Abrisham

**Street address**

Professor Hesabi Boulevard

**City**

Yazd

**Province**

Yazd

**Postal code**

8916871967

**Phone**

+98 35 3821 1093

**Email**

negin.abrisham@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Hooshang Mehrparvar

**Street address**

Bahonar Square, Yazd, Iran

**City**

Yazd

**Province**

Yazd

**Postal code**

8917693571

**Phone**

+98 35 3724 0171

**Email**

ah.mehrparvar@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Alimohammad RanjbarJamalabadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Professor Hesabi Boulevard, Yazd, Iran

**City**

Yazd

**Province**

Yazd

**Postal code**

8917693571

**Phone**

+98 35 3820 3865

**Email**

amranjbar@razi.tums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Alimohammad Ranjbar Jamalabadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Professor Hesabi Boolvar

**City**

Yazd

**Province**

Yazd

**Postal code**

8917693571

**Phone**

+98 35 3820 3865

**Email**

amranjbar@razi.tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Seyede Negin Abrisham

**Position**

Pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Jomhuri Boulevard, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8917944934

**Phone**

+98 35 3522 4310

**Email**

negin.abrisham@yahoo.com

## 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