

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Study of radioprotective effects of oral dose vitamin c to mitigate lymphocytopenia in patient undergoing radiotherapy for breast cancer

Protocol summary

Study aim

Study of radioprotective effects of oral dose vitamin c to mitigate lymphocytopenia in patient undergoing radiotherapy for breast cancer

Design

3 groups of 20 people that include a control group and groups are parallel, double blind, randomized

Settings and conduct

Patients in the Namazi Hospital are asked to take 4 hours after each radiotherapy session to take vitamin C which are blinded and three times to receive blood samples, then lymphocyte count and total antioxidant capacity are investigated

Participants/Inclusion and exclusion criteria

Entry requirements for breast cancer and the need for radiotherapy after mastectomy Exit Conditions Study the history of kidney disease and kidney stones and the use of multivitamins

Intervention groups

Oral doses of 150 and 250 mg of vitamin C and placebo of vitamin C

Main outcome variables

Counting lymphocytes, Mitigation lymphocytopenia in patient undergoing radiotherapy for breast cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161007030196N2**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32308113

Email address

stud6190006825@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-01, 1397/08/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of radioprotective effects of oral dose vitamin c to mitigate lymphocytopenia in patient undergoing radiotherapy for breast cancer

Public title

effects of vitamin c to mitigation the incidence of in patient undergoing radiotherapy for breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

breast cancer The need for radiotherapy after mastectomy

Exclusion criteria:

The history of kidney disease and kidney stones The use of multivitamins

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simplified randomization method is with a dice. Dicing for each person, if the number is 1 or 2 then the person is placed in group A and if 3-4 in group B and if number 5-6 in group C and then they are divided into three equal groups. There are two intervention groups and one placebo group, and the names are hidden inside sealed envelopes by someone except the researcher (like Hospital Collaborator).

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and researchers and clinical caregivers have been two-way blinded to the study groups using randomize.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice_Chancellor for Research and Technology ,Seventh Floor ,Central Building of Shiraz University of Medical Sciences ,Zand street

City
Shiraz

Province
Fars

Postal code
۷۱۳۳۶ ۷۱۳۴۸

Approval date
2018-07-29, 1397/05/07

Ethics committee reference number

1397.410

Health conditions studied

1

Description of health condition studied
breast cancer

ICD-10 code
C50.9

ICD-10 code description
Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description
Counting peripheral blood lymphocytes

Timepoint
Before entering the study, on days 14 and 28 after starting taking vitamin C

Method of measurement
Isolation of lymphocytes by centrifuge and counting by microscope

Secondary outcomes

1

Description
total antioxidant capacity

Timepoint
Before starting the intervention and day 28 after taking vitamin C

Method of measurement
Using the Eliza 96 Kit

Intervention groups

1

Description
Intervention group:

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
dr.seyed mohammad javad mortazavi
Street address
Namazai Square ,Zand Avenue ,Namazi Hospital
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Email
nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Central Building of Shiraz University of Medical Sciences , Facing Palestine Street ,Zand Streetet
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7134814336
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info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
dr.seyed mohammad javad mortazavi
Position
Professor
Latest degree
Ph.D.

Other areas of specialty/work

Medical Physics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Email

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available