Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 is1 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 caregivners 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_Chanceller for Research and Technology ,Seventh Floor ,Central Building of Shiraz University of Medical Sciences ,Zand street
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ 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 hosppital
Full name of responsible person
dr.seyed mohammad javad mortazavi
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Namazai Square ,Zand Avenue ,Namazi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
dr.seyed mohammad javad mortazavi
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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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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
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Other areas of specialty/work
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Person responsible for updating data

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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