Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Oral Whey Protein (Mā’ al-Jubn) on Radiation-Induced Dermatitis in Breast Cancer Patients

Protocol summary

Study aim
Investigating the Effect of Oral Whey Protein on Radiation-Induced Dermatitis in Breast Cancer Patients

Design
This double-blind randomized clinical trial will include 100 breast cancer patients undergoing adjuvant radiotherapy at Imam Reza Clinic and Namazi Hospital in Shiraz. Patients will be randomized into intervention and control groups (50 each). The intervention group will receive 30 g/day of whey protein while the control group will receive a matching placebo, from the start to the end of radiotherapy. Radiation-induced dermatitis will be assessed weekly using the EORTC/RTOG criteria.

Settings and conduct
Imam Reza Clinic and Namazi Hospital

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Pathologically confirmed breast cancer; previous breast-conserving surgery and eligibility for adjuvant radiotherapy; absence of systemic or skin diseases affecting wound healing or preventing radiotherapy; no concurrent chemotherapy or trastuzumab, with at least 3 weeks since the last chemotherapy cycle; no systemic corticosteroid use; no lactose intolerance or dairy allergy; and provision of informed consent. Exclusion Criteria: Withdrawal from the study; previous breast radiotherapy; development of a medical condition affecting study participation or radiotherapy tolerance; consumption of less than 70% of the prescribed supplement; serious adverse effects related to whey protein; discontinuation of radiotherapy for any reason; diagnosis of metastasis; or requirement for a tumor-bed boost or bolus.

Intervention groups
Whey protein

Main outcome variables
Reduction in the Incidence and Severity of Radiation-Induced Dermatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260807070559N1**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **prospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date
2026-08-10, 1405/05/19

Registrant information
Name
Seyede sahar Hashemi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 910 710 8271
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2028-08-22, 1407/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Oral Whey Protein (Mā’ al-Jubn) on Radiation-Induced Dermatitis in Breast Cancer Patients

Public title
investigating the Effect of Whey Protein on Radiation-Induced Dermatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pathologically confirmed breast cancer previous breast-conserving surgery, and eligibility for adjuvant radiotherapy No underlying condition contraindicating radiotherapy Written informed consent. No concurrent chemotherapy or trastuzumab (Herceptin) At least 3 weeks since the last chemotherapy cycle. Age 18–70 years No systemic or skin diseases affecting wound healing, such as diabetes mellitus or collagen vascular diseases No concurrent use of medications affecting wound healing, including systemic corticosteroids No lactose intolerance or dairy allergy.
Exclusion criteria:
Withdrawal from the study at any stage. Previous radiotherapy to the breast Development of a new medical condition affecting wound healing, radiotherapy tolerance, or continued participation Consumption of less than 70% of the prescribed supplement. Serious adverse effects related to whey protein. Need to discontinue radiotherapy for any reason. Diagnosis of metastasis during the study. Requirement for a boost or bolus.
Age
From **18 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
A permuted block randomization method with blocks of four will be used. There are six possible permutations for each block of four. Using a random-number table, a randomization list of 100 participants consisting of 25 blocks of four will be generated, determining the allocation sequence for the intervention and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The whey protein supplement and placebo will be prepared in identical containers with respect to appearance, color, size, taste, and packaging, and will be labeled only with codes A and B. Based on the patient’s identification number and the randomization list, the radiation oncology resident will provide the assigned container to the patient. Supplement or placebo administration will begin on the first day of radiotherapy and continue until the last day of treatment. Patients and study assessors (the radiation oncology resident and specialist) will be blinded to the assigned intervention; therefore, the study will be conducted as a double-blind trial. Group allocation codes will remain confidential until completion of data collection and analysis.
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
Karimkhanzand
City
Shraz
Province
Fars
Postal code
7134814336
Approval date
2026-08-08, 1405/05/17
Ethics committee reference number
35727

Health conditions studied

1

Description of health condition studied
Radiation-Induced Dermatitis
ICD-10 code
L58
ICD-10 code description
Radiodermatitis

Primary outcomes

1

Description
Reducing the severity of radiation-induced dermatitis
Timepoint
weekly
Method of measurement
Radiation dermatitis will be evaluated weekly by a radiation oncology resident and a radiation oncology

specialist, and in case of any disagreement, the specialist's opinion will be recorded as final.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiver of whey protein supplement
Category
Treatment - Other

2

Description
Control group: Oral placebo recipient
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Behnam kadkhodaei
Street address
Karimkhanzand
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+98 71 3612 5000
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namazee_inf@sums.ac.ir

2

Recruitment center
Name of recruitment center
Emam reza clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Behnam kadkhodaei
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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
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Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared because the study data are subject to patient confidentiality and privacy requirements. Only aggregated results will be reported.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable