

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 910 710 8271

Email address

s.sahar.hashemi1999@gmail.com

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.

Email
emamreza@sums.ac.ir

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

City

Shiraz

Province

Fars

Postal code

71936-13311

Phone

+98 71 3612 5000

Email

namazee_inf@sums.ac.ir

2

Recruitment center

Name of recruitment center

Emam reza clinic

Full name of responsible person

Behnam kadkhodaei

Street address

Karimkhan zand

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

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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President_d@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

Behnam Kadkhodaei

Position

Assistant professor

Latest degree

Specialist

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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