Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of a modified Mediterranean diet (ModiMed) combined with Pomegranate seed oil (punicic acid) supplementation on bone health and metabolic profile in post-menopause overweight and obese breast cancer survivors

Protocol summary

Study aim
Determining the effect of a modified Mediterranean diet (ModiMed) combined with Pomegranate seed oil supplement (punicic acid) supplementation on bone health and metabolic profile in post-menopause overweight and obese treated breast cancer survivors

Design
A controlled parallel-group, single-blind, randomized, clinical trial. Randomized block design using random array subset selection (RASS) software will be used.

Settings and conduct
120 postmenopausal women with treated breast cancer who are referred to the Sheikh Al-Raees Nutrition Clinic of Tabriz University of Medical Sciences and who meet the eligibility criteria will be included and will be randomly assigned to four groups. This will be done using opaque sealed envelopes to conceal the allocation process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Less than 6 months after complete treatment for breast cancer, cessation of menstruation for 12 months or more in the absence of specific causes other than natural menopause, body mass index of 25 kg/m2 and above Exclusion criteria: Being on medically prescribed diets, and planning on starting or stopping any chronic supplements or medications within six weeks before or throughout the study

Intervention groups
The first group: a modified Mediterranean diet with punicic acid supplementation for 6 weeks. The second group: a modified Mediterranean diet with punicic acid supplementation and a placebo for 6 weeks. The third group: punicic acid supplementation in addition to the American Cancer Society diet, for 6 weeks. The fourth or control group: the American Cancer Society diet with punicic acid supplementation and a placebo for 6 weeks.

Main outcome variables
Anthropometric and body composition indices, quality of life, serum levels of estradiol and testosterone, cancer-related fatigue, serum levels of bone turnover biomarkers, adiponectin, leptin, and resistin

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161022030424N12**
Registration date: **2025-06-07, 1404/03/17**
Registration timing: **prospective**

Last update: **2025-06-07, 1404/03/17**
Update count: **0**

Registration date
2025-06-07, 1404/03/17

Registrant information

Name
Neda Dolatkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-21, 1404/04/30

Expected recruitment end date
2026-07-21, 1405/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of a modified Mediterranean diet (ModiMed) combined with Pomegranate seed oil (punicic acid) supplementation on bone health and metabolic profile in post-menopause overweight and obese breast cancer survivors

Public title
Effect of a modified Mediterranean diet (ModiMed) combined with Pomegranate seed oil in post-menopause breast cancer survivors
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Less than 6 months after chemotherapy or radiation therapy of breast cancer (stage 0-IIIa) Cessation of menstruation for 12 months or more in the absence of specific causes other than natural menopause Body mass index of 25 kg/m2 and above Completion of all cancer-related treatments
Exclusion criteria:
Being on medically prescribed diets Planning on starting or stopping any chronic supplements or medications within six weeks before or throughout the study
Age
From **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use a stratified block randomization method for allocation. The computer-generated code generated using SAS software version 8.01 will be used to create a randomized sequence by a statistician outside the project's research team. Randomization will be stratified based on age and body mass index. Serially numbered opaque sealed packets will be used to ensure allocation
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding the patients is not feasible in this trial. A trained nutritionist will ban diet-related conversations between assessors and patients during the study. Outcome assessors and the person responsible for statistical analysis will be blinded to the type of interventions received until the end of the study
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5267845674
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.TBZMED.REC.1403.1100

Health conditions studied

1

Description of health condition studied
Treated breast cancer survivors
ICD-10 code
C50.9
ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
Weight
Timepoint
Weight measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Seca digital scale

2

Description
Body mass index
Timepoint
Estimated body mass index at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Calculation

3

Description
Body fat mass
Timepoint
Body fat mass measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Body composition analysis device

4

Description
Lean body mass
Timepoint
Lean body mass measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Body composition analysis device

Secondary outcomes

1

Description
Quality of life
Timepoint
Quality of life measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
functional assessment of cancer therapy-breast cancer (FACT-B)

2

Description
Cancer-related fatigue
Timepoint
Cancer-related fatigue measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Brief Fatigue Inventory

3

Description
Serum estradiol level
Timepoint
Serum estradiol level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

4

Description
Serum testosterone level
Timepoint
Serum testosterone level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

5

Description
Serum osteocalcin level
Timepoint
Serum osteocalcin level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

6

Description
Serum bone-specific alkaline phosphatase level
Timepoint
Serum bone-specific alkaline phosphatase level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

7

Description
Serum adiponectin level
Timepoint
Serum adiponectin level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

8

Description
Serum leptin level
Timepoint
Serum leptin level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

9

Description
Serum resistin level
Timepoint
Serum resistin level measurement at the beginning of the study (before the start of the intervention) and 6 weeks after the start of the intervention
Method of measurement
Biochemical analysis

Intervention groups

1

Description
Intervention group: Modified Mediterranean diet with Pomega 5 soft capsules from Vesha Daru Pars Herbal Pharmaceutical Company containing 500 mg of pomegranate seed oil (at least 10% panisic acid) for 6 weeks (The modified Mediterranean dietary intervention is a multi-variate intervention aimed at achieving low carbohydrate and low saturated fat intake, along with moderate protein and total fat intake. Consumption of extra-virgin olive oil, fish, raw and unsalted nuts (such as hazelnuts, almonds, walnuts, and pistachios), and non-starchy vegetables is unlimited.)
Category
Treatment - Other

2

Description
Intervention group: Modified Mediterranean diet with, Pomega 5 soft capsule placebo ,Vesha Daru Pars Herbal Pharmaceutical Company, for 6 weeks
Category
Treatment - Other

3

Description
Intervention group: Pomega 5 soft capsules from Vesha Daru Pars Herbal Pharmaceutical Company contain 500 mg of pomegranate seed oil (at least 10% panisic acid) along with the American Cancer Society (ACS; high fiber, low fat) diet for 6 weeks.
Category
Treatment - Other

4

Description
Control group: American Cancer Society diet with Pomega 5 soft capsules placebo, Vesha Daru Pars Herbal Pharmaceutical Company, for 6 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikh Al-Rais Clinic
Full name of responsible person
Neda Dolatkhah
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Parsa Street, Azadi Boulevard, Maralan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
Street address
Vice Chancellor for Research and Technology, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street
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Web page address
https://researchvice.tbzmed.ac.ir/?PageID=497
Grant name
Grant code / Reference number
75915
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Neda Dolatkhah

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Imam Reza Educational and Medical Center, opposite the Central Organization of the University, Golgasht Street

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Position
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Latest degree
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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
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