Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of glutamine supplementation on cardiomyopathy biomarkers, body composition changes and quality of life in breast cancer patients undergoing chemotherapy: a clinical trial study

Protocol summary

Study aim
Determining the Effect of Glutamine Supplementation on Biomarkers of Cardiomyopathy, Body Composition Changes, and Quality of Life in Breast Cancer Patients Undergoing Chemotherapy: A Clinical Trial Study.

Design
A double-blind randomized controlled trial, phase 3 with 46 patients, randomization with RAND excel function

Settings and conduct
Patients visiting the Mehraneh Clinic will be enrolled in the study using a easy sampling method. Patients will be randomly assigned to two groups. The packages containing the supplement and placebo will be coded with the numbers 1 or 2 by an individual not involved in the study, ensuring that both the researcher and the patients remain unaware of the type of supplement received by the participants.

Participants/Inclusion and exclusion criteria
Adult Women (18 years and older) with Breast Cancer Initiating Chemotherapy Visiting the Mehraneh Charity Association in Zanjan. Exclusion criteria: reporting excessive or insufficient food intake (800-4200 kcal), Body Mass Index (BMI) less than 18.5 or greater than 45, substance abuse or alcohol consumption at least once a week, pregnancy and lactation, CKD, CAD, MI, ESRD, DM, or liver disease.

Intervention groups
Glutamine supplementation and placebo will be administered for a duration of 8 weeks. A complete blood sample will be collected to assess the serum levels of the targeted biomarkers. Additionally, anthropometric data, demographic questionnaires, quality of life assessments, body composition analyses, and echocardiographic tests will be analyzed and completed before and after the intervention.

Main outcome variables
Levels of cTnT and CK-MB, anthropometric indices, body composition analysis, echocardiographic tests, and quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240916063060N1**
Registration date: **2025-01-26, 1403/11/07**
Registration timing: **prospective**

Last update: **2025-01-26, 1403/11/07**
Update count: **0**

Registration date
2025-01-26, 1403/11/07

Registrant information
Name
Ahmadreza Rasouli
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 24 3353 8571
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-08-22, 1404/05/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of glutamine supplementation on cardiomyopathy biomarkers, body composition changes and quality of life in breast cancer patients undergoing chemotherapy: a clinical trial study

Public title

Effect of glutamine in breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate Adult women (over 18 years of age) with breast cancer at the beginning of chemotherapy who referred to the Mehraneh Charity Association of Zanjan.

Exclusion criteria:

Report of food intake that is too much or too little (4200-800) kcal Body mass index less than 18.5 and more than 45 Drug use or alcohol consumption at least once a week Pregnancy and lactation Having CKD, CAD, MI, ESRD, DM, Liver disease

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization will be used. The size of all blocks will be equal. The randomization tool will be Random Sequence Generation (RAS) software. For concealment, random allocation using sealed opaque envelopes will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the packages containing supplements and placebo will be coded with numbers 1 or 2 by someone outside the study, and people will be assigned to one of the groups receiving code 1 or 2 based on the blocks. As a result, the researcher and the patients will be blinded.

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

Gholgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2025-01-13, 1403/10/24

Ethics committee reference number

IR.TBZMED.REC.1403.848

Health conditions studied

1

Description of health condition studied

سرطان پستان

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Serum cTnT level

Timepoint

Before the start of the study and 2 months after the intervention

Method of measurement

ELISA

2

Description

Serum CK-MB level

Timepoint

Before the start of the study and 2 months after the intervention

Method of measurement

ELISA

3

Description

Echocardiography test

Timepoint
Before the start of the study and 2 months after the intervention
Method of measurement
Echocardiography device

4

Description
Body composition analysis
Timepoint
Before the start of the study and 2 months after the intervention
Method of measurement
Body composition analyzer

5

Description
Food frequency
Timepoint
Before the start of the study and 2 months after the intervention
Method of measurement
Food frequency questionnaire

6

Description
Anthropometric index(weight, height, and Body Mass Index)
Timepoint
Before the start of the study and 2 months after the intervention
Method of measurement
Scale and Stadiometer

Secondary outcomes

1

Description
Quality of life
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Questionnaire (QLQ-C30)

Intervention groups

1

Description
Intervention group: The intervention group will receive 5 grams of glutamine powder daily for a duration of 8 weeks. Glutamine will be purchased from Karen Company. All patients will be monitored for glutamine consumption using a weekly checklist and reminder messages.
Category
Prevention

2

Description
Control group: The control group will receive 5 grams of placebo powder daily for a duration of 8 weeks. The placebo will be purchased from Karen Company. All patients will be monitored for placebo consumption using a weekly checklist and reminder messages.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehraneh charity
Full name of responsible person
Ahmadreza Rasouli
Street address
Mehraneh Central Building, Mehraneh Boulevard, Zanjan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Alizadeh
Street address
Faculty of Nutrition and Food sciences, Tabriz University of Medical Sciences, Attar Neishabouri St., Tabriz, Iran
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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
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
Ahmadreza Rasouli
Position
Ph.D student
Latest degree
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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