Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect Of Coenzyme Q10 Supplementation On Serum LevelsOf Interleukin 6, 8, Vascular Endothelial Growth Factor And Quality Of Life In Breast Cancer Women Undergoing Tamoxifen Therapy

Protocol summary

Summary

Objective:Effect of co enzyme Q10 supplementation on serum levels of interleukin 6, 8, vascular endothelial growth factor and quality of life in breast cancer women undergoing tamoxifen therapy Study design: Randomized, double-blind(blinding for patients and scholar), placebo controlled The study population: Inclusion criteria : diagnosed with positive estrogen receptor breast cancer by a physician; chemotherapy and radiation therapy, and a history of taking tamoxifen for at least a year; Not taking Q10 supplement and other antioxidants such as vitamin E; Willingness to comply with all interventions and follow-up procedures; Non-pregnant and non-lactating; Having no uncontrolled diseases such as diabetes and thyroid; Not taking non-prescription drugs, corticosteroids, statins Exclusion criteria : metastasis; partial or total mastectomy and not having any of the above entry criteria Sample size: 60 Intervention or interference in the study: Effect of co enzyme Q10 on serum levels of interleukin 6, 8, vascular endothelial growth factor and quality of life Intervention time: 2 months The primary outcome or consequences of the study: variation of serum interleukin 6 and 8, VEGF and quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042021874N1**
Registration date: **2015-10-08, 1394/07/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-08, 1394/07/16

Registrant information

Name

Nazanin Zahrooni

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 7587

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Recruitment status

Recruitment complete

Funding source

Nutrition and Metabolic Disorders Research Center

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Coenzyme Q10 Supplementation On Serum LevelsOf Interleukin 6, 8, Vascular Endothelial Growth Factor And Quality Of Life In Breast Cancer Women Undergoing Tamoxifen Therapy

Public title

The effect of Q10 on breast cancer treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : diagnosed with positive estrogen

receptor breast cancer by a physician; chemotherapy and radiation therapy, and a history of taking tamoxifen for at least a year; Not taking Q10 supplement and other antioxidants such as vitamin E; Willingness to comply with all interventions and follow-up procedures; Non-pregnant and non-lactating; Having no uncontrolled diseases such as diabetes and thyroid; Not taking non-prescription drugs, corticosteroids, statins Exclusion criteria : metastasis; partial or total mastectomy and not having any of the above entry criteria

Age
From **19 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
No other

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Ahvaz Medical University

Street address
Clinical trial research center,Jondi-shapoor Medical University of Ahvaz

City
Ahvaz

Postal code

Approval date
2015-07-25, 1394/05/03

Ethics committee reference number
ir.ajums.rec.1394.246

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C44.5,C50.

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Quten serum levels

Timepoint
Before intervention

Method of measurement
Pg/ml using biochemical kits

2

Description
Interluekin 6 serum levels

Timepoint
Before and after intervention

Method of measurement
Pg/ml using biochemical kits

3

Description
Interluekin 8 serum levels

Timepoint
Before and after intervention

Method of measurement
Pg/ml using biochemical kits

4

Description
VEGF serum levels

Timepoint
Before and after intervention

Method of measurement
Pg/ml using biochemical kits

5

Description
Quality of life

Timepoint
Before and after intervention

Method of measurement
Breast cancer Quality of Life Questionnaire

Secondary outcomes

1

Description
weight

Timepoint
Before and after intervention

Method of measurement
Scale

2

Description
Dietary intake
Timepoint
Before and after intervention
Method of measurement
Three-day record

Intervention groups

1

Description
Intervention group of patients: 100 mg Q10 daily for 2 months
Category
Treatment - Drugs

2

Description
Intervention group of non patients: 100 mg Q10 daily for 2 months
Category
Treatment - Drugs

3

Description
Control group of patients: placebo for 2 months
Category
Treatment - Drugs

4

Description
Control group of non patients: placebo for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Dr.Ahmad Ahmadzadeh
Street address
Shafa Hospital, Golestan
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address
Research Center office, Research and Technology Center, Ahvaz University of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Ahvaz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Nutrition and Metabolic Disorders Research Center
Full name of responsible person
Dr.Seyed Ahmad Hosseini
Street address
Second floor, Paramedical Faculty, Ahwaz University of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition and Metabolic Disorders Research Center
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Paramedical Faculty

Full name of responsible person
Nazanin Zahrooni
Position
M.Sc. of Nutrition
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty