

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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

Email address

zahrooni.n@ajums.ac.ir

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, 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

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

Other areas of specialty/work**Street address**

Paramedical Faculty

City

Ahvaz

Postal code**Phone**

+98 916 802 8250

Fax**Email**

Zahrooni.n@ajums.ac.ir;

Naziincredible@rocketmail.com

Web page address

Seyedahmadhosseini@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Paramedical faculty

Full name of responsible person

Nazanin Zahrooni

Position

M.Sc. of Nutrition

Other areas of specialty/work**Street address**

Paramedical faculty

City

Ahvaz

Postal code**Phone**

+98 916 802 8250

Fax**Email****Web page address****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***Person responsible for scientific inquiries****Contact****Name of organization / entity**

Paramedical faculty

Full name of responsible person

Dr. Seyad Ahmad Hosseni

Position

PhD of Clinical Biochemistry

Other areas of specialty/work**Street address**

Paramedical faculty

City

Ahvaz

Postal code**Phone**

+98 916 309 7944

Fax**Email**