

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of omega- 3 on quality of life,menopausal sumptoms and sextual dysfunction in tamoxifen consumer women with breast cancer that refer to motahhari breast cancer clinic in 1390

Protocol summary

Summary

The aim of this study,was to omega-3 effect on quality of life, menopausal symptoms and sexual dysfunction in women taking tamoxifen that had breast cancer. Samples in this study were 140 women with breast cancer complained of the side effects of tamoxifen that after completing the questionnaire were entering the study and And were divided into two groups. Omega-3 group and the placebo group that received a questionnaire before and after completing a period of three months and then were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104052515N3**
Registration date: **2012-08-09, 1391/05/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Maasumeh Kaviani

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for reaserch of shiraz university of medical sciences

Expected recruitment start date

2011-11-19, 1390/08/28

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega- 3 on quality of life,menopausal sumptoms and sextual dysfunction in tamoxifen consumer women with breast cancer that refer to motahhari breast cancer clinic in 1390

Public title

The effect of omega-3 on the side effects of tamoxifen in women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Medical record review identified female patients who were initially diagnosed as stage 1 and 2 with breast cancer prior to menopause age or menopause are not related to medication or surgery, married, be literate, signed and confirmed consent form, completed adjuvant treatment such as chemotherapy, hormonal therapy with tamoxifen or suffered by tamoxifen treatment side effects such as; hot flashes, sexual dysfunction, night sweats, negative impact on life quality, that met the inclusion criteria. After deletion of patients who met specific exclusion criteria such as; high blood pressure,

blood lipids, renal and thyroid dysfunction, history of allergy to Ω -3, using medication or food complementary for the purpose of preventing or reducing complications and/or side effects of tamoxifen treatment, using medication to treat mental disorder, having severe and progressive disease(s), disease relapse, those patients who were initially or later diagnosed with advanced stages (>2) of breast cancer and finally those one unwillingness to continue participation in research.

Age

To 50 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 140

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences and Health Services

Street address

Shiraz- Namazi Square- Fatemia School of Nursing Midwifery

City

Shiraz

Postal code

Approval date

2011-10-24, 1390/08/02

Ethics committee reference number

CT-90_5786

Health conditions studied

1

Description of health condition studied

Quality of life, side effect of menopause, sexual dysfunction

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Hot flashes

Timepoint

before intervention and three months after intervention

Method of measurement

part of the grin questionnaire

2

Description

Night sweats

Timepoint

before intervention and Three months after intervention

Method of measurement

part of the grin questionnaire

3

Description

Quality of life

Timepoint

before intervention and three months after intervention

Method of measurement

QLQ-C30 questionnaire

4

Description

Sexual dysfunction

Timepoint

before intervention and three months after intervention

Method of measurement

FSFI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

omega-3 1000 mg capsule one time a day for three months

Category

Prevention

2

Description

omega-3 1000 mg capsule one time a day for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Breast clinic

Full name of responsible person

Rezvan Heidari

Street address

Shiraz- Namazi square- Motahhari breast clinic

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shiraz university of medical science

Full name of responsible person

Mr. Kambiz Skandari

Street address

Shiraz- Namazi Square- Building university of Medical Science

City

Shiraz

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, shiraz university of medical science

Proportion provided by this source

100

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

shiraz university o medical science

Full name of responsible person

Maasumeh Kaviani

Position

MD of midwifery

Other areas of specialty/work

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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