

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of individual diet therapy on the side effects of chemotherapy and the quality of life in patient with breast cancer

Protocol summary

Summary

The present study aims to determine an appropriate individual diet therapy to improve breast cancer patients' nutritional status, to enhance their life quality and health level, to overcome their nutrition barriers and to reduce their medical expences. This study is a randomized clinical trial. The participants of the study must be woman over the age of 18 who have undergone chemotherapy once or three times, howere, those who have to follow a special diet plan, or suffer from diseases other tahn cancer will be excluded from the study. The participants of the study will be 70 woman who are going to be treated by a special nutritional diet therapy for about 2 months. Additionally, at the bigining and at the end of study, the chemotherapy side effects such as, anorexia, adnauseam, diarrhea, constipation, serum albumin, liver enzyme, ferritin, hemoglobin and alkanin phosphatose will be measured and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607193236N7**

Registration date: **2017-07-08, 1396/04/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-08, 1396/04/17

Registrant information

Name

Zohreh Mazloom

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1008

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Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2016-07-23, 1395/05/02

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of individual diet therapy on the side effects of chemotherapy and the quality of life in patient with breast cancer

Public title

Individual diet therapy on prevention of the side effect of chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria : Breast cancer patients receiving chemotherapy with fixed-position; age greather than 18 years old; persian Language; people who do not follow the specific treatment regime; Patients with metastatic breast cancer who are not exclusion criteria: People with diseases such as heart disease, diabetes or neurodegenerative diseases such as Parkinson's affects .

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Postal code

Approval date

2016-05-29, 1395/03/09

Ethics committee reference number

IR.SUMS.REC.1395.61

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Inflammation of the mouth

Timepoint

befor and after intervention

Method of measurement

nutritional barriers questionnaire

2

Description

Change sense of taste and smell

Timepoint

befor and after intervention

Method of measurement

nutritional barriers questionnaire

3

Description

Diarrhea

Timepoint

befor and after intervention

Method of measurement

nutritional barriers questionnaire

4

Description

constipation

Timepoint

befor and after intervention

Method of measurement

nutritional barriers questionnaire

5

Description

dysphagia

Timepoint

befor and after intervntion

Method of measurement

nutritional barriers questionnaire

6

Description

loss of appetite

Timepoint

befor and after intervention

Method of measurement

nutritional barriers questionnaire

7

Description

weight change

Timepoint

befor and after intervention

Method of measurement

Balance - kg

8

Description

BMI

Timepoint

befor and after intervention

Method of measurement

weight divide into height2

9

Description

alb

Timepoint

befor and after intervention

Method of measurement

Standard enzymatic method

10

Description

SGOT,SGPT

Timepoint

befor and after intervention

Method of measurement

Standard enzymatic method

11

Description

alka.phos

Timepoint

befor and after intervention

Method of measurement

Standard enzymatic method

12

Description

ferritin

Timepoint

befor and after intervention

Method of measurement

Standard enzymatic method

13

Description

hb

Timepoint

befor and after intervention

Method of measurement

Standard enzymatic method

14

Description

malnutrition

Timepoint

befor and after intervention

Method of measurement

PG-SGA questionnaire

Secondary outcomes

1

Description

quality of life

Timepoint

befor and after intervention

Method of measurement

EROTIC-QLQ-C30 questionnaire

Intervention groups

1

Description

In the intervention group therapy interventions including diet and nutritional advice in 2 month and pamphlets are provided in the control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

Kiana Parnian

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

The Headquarters Of Shiraz University Of Medical Sciences, Opposite of Palestine Street, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University Of Medical Sciences

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

Name of organization / entity

Shiraz University Of Medical Sciences, Faculty Of
Nutrition and Food Sciences

Full name of responsible person

Kiana Parnian

Position

Master of Science in Nutrition

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

Department of Nutrition and Food Science, Razi blvd

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Person responsible for updating data

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Full name of responsible person

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences, Faculty of
Nutrition and Food Sciences

Full name of responsible person

Dr Zohreh Mazloom

Position

PhD, nutritional sci - professor

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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