

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 alkaalin 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

##### Email address

zmazloom@sums.ac.ir

##### 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

**City**

Shiraz

**Postal code****Phone**

+98 713751005

**Fax****Email**

kiana.parnian.p@gmail.com

**Web page address****Fax****Email**

zohreh.mazloom@gmail.com

**Web page address**

## Person responsible for updating data

### 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

**City**

Shiraz

**Postal code****Phone**

00

**Fax****Email****Web page address**

## 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

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

Department of Nutrition and Food Science, Razi blvd

**City**

Shiraz

**Postal code****Phone**

+98 71 3725 1001

## 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*