

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effects of conjugated fatty acids supplement on metabolic parameters in benign breast disease in concerning with the polymorphism of PPAR $\gamma$ : a randomized controlled-clinical trial

#### Protocol summary

##### Summary

(1)Objectives: The effects of conjugated fatty acids (C.F.A) supplement on metabolic parameters in patients with benign breast tumor in concerning with the polymorphism of PPAR $\gamma$  gene. (2)Key inclusion criteria: Pathology report or sonography confirmation for benign breast tumors; Tendency to participate in study; 25-47 years old; Body mass index (B.M.I) less than the ratio of 35 kilogram to squared meter. (3)Key exclusion criteria: Being in lactation and pregnancy conditions; Being menopause; Taking insulin or oral anti-diabetic drug in each phase of the study by patients; Malignant diseases or any history of malignancy; Thyroid disorders; Acute liver failure; Getting hormonal disorders before benign breast disease (B.B.D) diagnosis (such as poly cystic ovary syndrome, type 1 diabetes, hypoglycemia, and adrenal gland disorders); Any sever gastrointestinal disease; History of chemotherapy, radiotherapy, and hormone therapy; Taking glucocorticoid, anticoagulant, antiepileptic, contraceptive drugs, and hormone replacement therapy (H.R.T); Taking fish liver oil supplement more than 2,000 mg per day; Being heavy smoker in the past year before the diagnosis of B.B.D; Vigorous physical activity. (4)Participants and sample size: This study will be conducted on 50 women with B.B.D who meet inclusion criteria. Patients will be randomly divided into a treatment group of 25 cases and placebo of 25 cases based on type of disease. (5)Interventions: In a parallel manner, treatment group will receive 1000 mg per day CFA-containing oil (one 1000 mg soft-gel capsule) with 10 IU vitamin E and placebos will consume 1000 mg per day combined inert oil (one 1000 mg soft-gel capsule containing 350 mg sunflower oil, 350 mg palm olein, 300 mg corn oil) with 10 I.U vitamin E for 13 weeks. Placebo capsules will be virtually similar to C.F.A capsules. (6)Primary outcomes: measurement of metabolic parameters including insulin,

glucose, peptide C, PPAR $\gamma$ , IGFBP-3, and IGF-1 at baseline and endpoint of intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014050411335N3**

Registration date: **2014-05-18, 1393/02/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-18, 1393/02/28

##### Registrant information

##### Name

Saeed Pirouzpanah

##### Name of organization / entity

Nutrition Faculty, Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41133575803

##### Email address

pirouzpanahs@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-06-22, 1394/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of conjugated fatty acids supplement on metabolic parameters in benign breast disease in concerning with the polymorphism of PPAR $\gamma$ : a randomized controlled-clinical trial

**Public title**

The effects of conjugated fatty acids supplement on benign breast disease

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Pathology report or sonography confirmation for benign breast tumors; Tendency to participate in study and completing the informed consent form; 25-47 years old; Body mass index (B.M.I) less than the ratio of 35 kilogram to squared meter. Exclusion criteria: Being non-respondent (low compliance) during study; Consumption of less than 85% of supplements (oil capsules); Being in lactation and pregnancy conditions; Being menopause; Taking insulin or oral anti-diabetic drug in each phase of the study by patients; Malignant diseases or any history of malignancy; Thyroid disorders; Acute liver failure such as cirrhosis and viral infection; Getting hormonal disorders before benign breast disease (B.B.D) diagnosis (such as poly cystic ovary syndrome, type 1 diabetes, hypoglycemia, and adrenal gland disorders); Growth hormone disorders and severe congenital anomalies; Peptic ulcer disease and helicobacter pylori infection and any sever gastrointestinal disease such as irritable bowel syndrome and inflammatory bowel disease; Following a vegetarian diet (vegan or lacto-ovo vegetarian); History of chemotherapy, radiotherapy, and hormone therapy; Taking glucocorticoid, anticoagulant, antiepileptic, contraceptive drugs, and hormone replacement therapy (H.R.T); Taking fish liver oil supplement more than 2,000 mg per day; Taking vitamin A supplement; Being heavy smoker in the past year before the diagnosis of B.B.D; Alcohol consumption; Vigorous physical activity.

**Age**

From **25 years** old to **47 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Faculty of Nutrition, Tabriz University of Medical Sciences

**Street address**

Attar Neishaboori Ave., Golgasht St

**City**

Tabriz

**Postal code****Approval date**

2014-04-14, 1393/01/25

**Ethics committee reference number**

936

**Health conditions studied****1****Description of health condition studied**

Benign breast tumor

**ICD-10 code**

D24

**ICD-10 code description**

Benign neoplasm of breast

**Primary outcomes****1****Description**

Measurement of metabolic parameters

**Timepoint**

Baseline and the endpoint of study

**Method of measurement**

Fasting plasma levels of IGF-1 and glucose and fasting serum levels of IGFBP-3, C-Peptide, Insulin, and PPAR $\gamma$

**Secondary outcomes****1****Description**

Anthropometric parameters

**Timepoint**

Baseline, week 4, week 8, and the end of study

**Method of measurement**

Waist circumference, body mass index, and waist to hip ratio

## 2

### **Description**

Physiologic variations

### **Timepoint**

Baseline, week 4, week 8, and the end of study

### **Method of measurement**

Systolic and diastolic blood pressure

## **Intervention groups**

### 1

### **Description**

1000 mg per day CFA-containing oil (one 1000 mg soft-gel capsule) with 10 IU vitamin E for 13 weeks.

### **Category**

Treatment - Drugs

### 2

### **Description**

1000 mg per day combined inert oil (one 1000 mg soft-gel capsule containing 350 mg sunflower oil, 350 mg palm olein, 300 mg corn oil) with 10 IU vitamin E for 13 weeks.

### **Category**

Placebo

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Noor-Nejat hospital

#### **Full name of responsible person**

Neda Rezvani

#### **Street address**

Hafez St., Azadi Blv

#### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Vice-chancellor for Research, Tabriz University of Medical Sciences

#### **Full name of responsible person**

Dr. Pourghasem Gargari

#### **Street address**

Attar Neishaboori Ave., Golgasht St

#### **City**

Tabriz

### **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, Tabriz 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**

## **Person responsible for scientific inquiries**

### **Contact**

#### **Name of organization / entity**

Faculty of Nutrition, Tabriz University of Medical Sciences

#### **Full name of responsible person**

Dr. Saeed Pirouzpanah

#### **Position**

Ph.D in Nutrition science

#### **Other areas of specialty/work**

#### **Street address**

Faculty of Nutrition, Attar Neishaboori Ave., Golgasht St

#### **City**

Tabriz

#### **Postal code**

#### **Phone**

+98 41 1335 7580

#### **Fax**

#### **Email**

Pirouzpanahs@tbzmed.ac.ir

#### **Web page address**

## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

Faculty of Nutrition, Tabriz University of Medical Sciences

#### **Full name of responsible person**

Neda Rezvani

#### **Position**

MSc student of Nutrition

#### **Other areas of specialty/work**

#### **Street address**

Faculty of Nutrition, Attar Neishaboori Ave., Golgasht St

#### **City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7580

**Fax**

**Email**

neda7rezvani@yahoo.com

**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*