Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of conjugated fatty acids supplement on metabolic parameters in benign breast disease in concerning with the polymorphism of PPARγ: 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 PPARγ 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, PPARγ, 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

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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 PPARγ: 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 PPARγ

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
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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

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Name of organization / entity
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Person responsible for updating data

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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