

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effects of berberis vulgaris juice on plasma hormonal-metabolic parameters and PPAR- γ gene expression level in patients with benign breast tumor: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: The effect of berberis vulgaris juice on plasma level of hormonal-metabolic parameters, plasma level and gene expression of PPAR- γ in patients with benign breast tumor (2) Design: A randomized controlled clinical trial. (3) Setting and conduct: 80 patients with benign breast tumor will be randomly divided into either intervention or control group. In this study, observers in laboratory and nurses for distributing the beverages will be blinded. (4) Participants: The inclusion criteria: Histopathological confirmed benign breast; 15-45 years old; Tendency to corporation in study; Completing informed consent form; Passing atleast 2 year from diagnosing disease; BMI less than the ratio of 35 kilogram to squared meter; Moderately active; Lack of menopause. Exclusion criteria: Energy intake range out of 500-3500; History of consumption cigarette in recent 1 year before diagnosing the disease; Acute chronic disease like other cancers, Cardiovascular disease, Renal disease, Liver disease, Hyperthyroidism and other hormonal disorder before diagnosing the disease (pcos, type 1 diabetes, Hypoglycemia, Adrenal gland malfunction); Having any kind of bleeding & trauma by self reporting or physician; History of other benign neoplasms; Pregnancy and lactation; Consumption of drugs like glucocorticoids, Blood anticoagulants, Epilepsy-related drugs, HRTs, Fish oil supplements more than 2000 mg per day. (5) Intervention: Subjects in intervention group will receive 480 ml berberis vulgaris juice in lunch & dinner meal. Also In control group subjects will receive 480 ml placebo both in lunch & dinner meal. (6) Main outcome measures (variables): Measuring plasma levels of hormonal-metabolic parameters (IGF-1, Insulin, C-peptide, FBS, IGFBP-1, IGFBP-3) and plasma level and gene expression of PPAR-gamma at baseline & endpoint of intervention

General information

Acronym

BBT

IRCT registration information

IRCT registration number: **IRCT2012110511335N2**

Registration date: **2013-07-10, 1392/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-10, 1392/04/19

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, Faculty of Nutrition, Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of berberis vulgaris juice on plasma hormonal-metabolic parameters and PPAR- γ gene expression level in patients with benign breast tumor: a randomized controlled clinical trial

Public title

The effects of berberis vulgaris juice on plasma hormonal-metabolic parameters and PPAR- γ gene expression level in patients with benign breast tumor: a randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Participants: The inclusion criteria: Histopathological confirmed benign breast; 15-45 years old; Tendency to corporation in study; Completing informed consent form; Passing atleast 2 year from diagnosing disease; BMI less than the ratio of 35 kilogram to squared meter; Moderately active; Lack of menopause. Exclusion criteria: Energy intake range out of 500-3500; History of consumption cigarette in recent 1 year before diagnosing the disease; Acute chronic disease like other cancers; Cardiovascular disease like: Renal disease, liver disease, Hyperthyroidism and other hormonal disorder before diagnosing the disease (pcos, type 1 diabetes, Hypoglycemia, adrenal gland malfunction); Having any kind of bleeding & trauma by self reporting or physician; History of other benign neoplasms; Pregnancy and lactation; Consumption of drugs;like glucocorticoids, blood anticoagulants, Epilepsy-related drugs, HRTs, Fish oil supplements more than 2000 mg per day.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Neyshabori St., Golgasht St.,

City

Tabriz

Postal code**Approval date**

2013-05-28, 1392/03/07

Ethics committee reference number

1960-4-5

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**

Plasma levels of hormonal-metabolic parameters (IGF-1, Insulin, C-peptide, FBS, IGFBP-1, IGFBP-3) and plasma level and gene expression of PPAR-gamma

Timepoint

Baseline and endpoint of the intervention

Method of measurement

Electrochemiluminescence

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

Gene expression of PPAR-gamma

Timepoint

Baseline and endpoint of the intervention

Method of measurement

Real time RT-PCR

Intervention groups**1****Description**

Control groups: 480 ml similar to intervention(suger: 55gr, vitamin c: 80 mg) both in lunch & dinner meal (a glass in each meal equal to 240ml) for 8 weeks.

Category

Treatment - Drugs

2**Description**

Intervention Group: 480 ml berberis vulgaris juice(protein:600mg/500ml; Carbohydrates:55gr/500ml; vitamin c:80mg/500ml; Calcium:50mg/500ml; Sodium:100mg/500ml; fat:10mg/500ml) both in lunch & dinner meal (a glass in each meal equal to 240ml) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Noor-Nejat hospital

Full name of responsible person

Hospital manager

Street address

Hafez st., Azadi Blvd., Tabriz,

City

Tabriz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice Chancellor for research, Faculty of Nutrition,
Tabriz University of Medical Sciences

Full name of responsible person

Dr. Shakouri, Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar
Neysabori St., 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, Faculty of Nutrition, 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

Nutrition, PhD

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

Faculty of Nutrition, Tabriz University of Medical
Sciences, Attar Neysabori St., 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

Dr. Saeed Pirouzpanah

Position

Nutrition, PhD

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

Faculty of Nutrition, Tabriz University of Medical
Sciences, Attar Neysabori St., Golgasht St

City

Tabriz

Postal code**Phone**

+98 41 1335 7580

Fax**Email**

pirouzpanahs@tbzmed.ac.ir

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