

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effects of berberis vulgaris juice on plasma hormonal-metabolic parameters and PPAR- $\gamma$ 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- $\gamma$  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- $\gamma$  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- $\gamma$  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 centers**1**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 sources**1**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  
Neyshabori 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**

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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**

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**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*