

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effect of tripterygium wilfordii roots supplementation on the metabolic status, anthropometric parameters and serum levels of leptin and Chemerin in obese women

Protocol summary

Summary

The purpose of this clinical trial is to evaluate the effect of tripterygium wilfordii roots supplementation on the metabolic status, anthropometric parameters and serum levels of leptin and Chemerin in obese women. Sample size is 44 person. This trial is a randomized, double-blind, placebo-controlled clinical trial. Blinding will be performed for patients and the study researchers. After meeting the inclusion and exclusion criteria, patients will allocated randomly (by random numbers table) into two intervention and control groups. At the beginning of the study, five ml of blood (after 8-12 hours of fasting) will be taken. After determining the persons to the intervention and control groups, a cloudy and closed envelopes will be used for allocation to two groups. For everyone in the envelopes, the capsule will be similar. 200 mg capsules with people on a daily basis will eat lunch. Fasting blood was used for lipid Parameters profile, leptin, insulin and Chemerin. Blood pressure also was measured.. They will be evaluated based on the following criteria: women 50-25 years of age and BMI of between 30- 40 Exclusion criteria: the use of lipid lowering agents; weight loss drugs and addiction

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610084105N29**
Registration date: **2017-07-01, 1396/04/10**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-01, 1396/04/10

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-08-11, 1396/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tripterygium wilfordii roots supplementation on the metabolic status, anthropometric parameters and serum levels of leptin and Chemerin in obese women

Public title

The effect of the tripterygium wilfordii on obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 25-50 year old women; BMI of between 30- 40; willingness to cooperate. Exclusion criteria: use

of lipid lowering agents; use of body weight loss medications; Addiction and Smoking; Menopause; Sensitivity to placebo; cancer; cardiovascular disease; liver disorders; kidney disease and anemia; use of antioxidant supplements, fish oil supplements and alcohol; pregnancy and lactation

Age

From **25 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Ghol-Ghasht Ave, Azadi St, Tabriz

City

Tabriz

Postal code

Approval date

2017-05-25, 1396/03/04

Ethics committee reference number

IR.TBZMED.REC.1396.179

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

HDL

Timepoint

At baseine and after 3 month of intervention

Method of measurement

Enzymatic and colorimetric method

2

Description

whight

Timepoint

At baseine and after 3 month of intervention

Method of measurement

scale

3

Description

LDL

Timepoint

At baseine and after 3 month of intervention

Method of measurement

Enzymatic and colorimetric method

4

Description

Triglyceride

Timepoint

Beginning of the study and after three months

Method of measurement

Enzymatic and colorimetric method

5

Description

Total Cholesterol

Timepoint

At baseine and after 3 month of intervention

Method of measurement

Enzymatic and colorimetric method

6

Description

Serum Chemerin

Timepoint

At baseine and after 3 month of intervention

Method of measurement

ELISA

7

Description

Serum Leptin

Timepoint

At baseine and after 3 month of intervention

Method of measurement

ELISA

8

Description

BMI

Timepoint

At baseine and after 3 month of intervention

Method of measurement

W/H.t2

9

Description

FBS

Timepoint

At baseine and after 3 month of intervention

Method of measurement

Glucose oxidase enzymatic and colorimetric

10

Description

Insulin levels

Timepoint

At baseine and after 3 month of intervention

Method of measurement

Enzymatically using autoanalyzer

11

Description

Insulin resistance

Timepoint

At baseine and after 3 month of intervention

Method of measurement

HOMAIR

Secondary outcomes

1

Description

Food intake

Timepoint

At baseine of the study, sixth week and three months later

Method of measurement

The questionnaires and Software nutrition 4

2

Description

blood pressure

Timepoint

At baseine of the study, sixth week and three months later

Method of measurement

Standard mercury manometer

3

Description

Physical activity

Timepoint

At baseine of the study, sixth week and three months later

Method of measurement

The International physical activity questionnaire

Intervention groups

1

Description

Intervention group: patients will recieve a daily capsule containing 200 mg of tripterygium wilfordii root powder, for three months. Capsules should taken with food and a glass of water.

Category

Treatment - Drugs

2

Description

Control group: patients will receive a placebo capsule, daily for three months..

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of nutrition Kermanshah University of Medical Sciences

Full name of responsible person

Dr mostafa nachvak

Street address

Faculty of nutrition Kermanshah University of Medical Sciences, Dolatabad, Isar Sq, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi, Research Assistant of Tabriz University of Medical Sciences

Street address

Ghol-Ghasht Ave.,Azadi St.,Tabriz.

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****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mousavi Mele

Position

MSc. Student of Nutrition

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Fax**Email****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