Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Country
Iran (Islamic Republic of)
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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 poweder, 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

Other areas of specialty/work

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MSC student of nutrition

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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