

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The study randomized clinical trial for comparing the effect of herbal supplement based on traditional medicine versus placebo with weight loss diet on some biochemical parameters & Anthropometric indices in obese subjects

Protocol summary

Summary

The study is a randomized double-blind clinical trial for comparing the effect of herbal supplement based on traditional medicine versus placebo with weight loss diet on some biochemical parameters and Anthropometric indices in obese subjects. Patients with a BMI more than 30 and age range 20-50 years old will be included. The study aim is gradual weight loss that will maintain ideal body weight. In this study drug on traditional Iranian medicine (buali-formula composed of Carum carvi, Origanum vulgare, Ruta Graveolen, Trachyspermum copticum; component equal weight to mixed) is investigated. In this clinical trial, 68 participation (34 patients receiving the drug group and 34 in the control group) according to random allocation inclusion and exclusion criteria will be recruited for two months. The medication will be used as much as 3 capsules for daily. The control group received placebo 3 a daily. All the participants will complete the consent form. Probable side effects will be assessment during intervention and assessment of Primary outcome is control at base line, 4weeks, 8 weeks and after intervention. Primary outcome are: weight, waist and hip circumference and secondary outcome are include [Fasting blood glucose, Cretinine, Cholesterol, Triglyceride, high-density lipoprotein, low- density lipoprotein, Uric acid, hs-CRP, IL-6, TNF α , Leptin, grelin] assessment at entry and end of intervention. In addition to completing on arrival the General temperament of intervention and Nutrition counseling and completion of a 3-day food records and supply information in the entry and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307272017N17**

Registration date: **2014-06-04, 1393/03/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-04, 1393/03/14

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

ostadrahimi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study randomized clinical trial for comparing the effect of herbal supplement based on traditional medicine versus placebo with weight loss diet on some biochemical parameters & Anthropometric indices in obese subjects

Public title

Effect of herbal supplement based on traditional medicine versus placebo with weight loss diet on some biochemical parameters & Anthropometric indices in obese subjects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having BMI more than or equal 30; Age between 20 to 50 years old; Inform consent signed by the patient; Those who can over the next two months two times refer for take drugs and laboratory examination ; Waist circumference > 102 cm (men) or > 88 cm (women). Exclusion Criteria: Inform consent not signed by the patient; Those who can not over the next two months two times refer for take drugs and laboratory examination; Heavy Smoking(More than twenty cigarettes per daily); Diabetes mellitus; Patients with coronary heart vascular disease ;Patients with proven malignancy; Asthma; Chronic cough; Chronic lung inflammatory and bowel disease; Fever of unknown origin; Patients with a history of chronic kidney and liver disease(Exception fatty liver and not including obesity, allergies, skin problems, or occasional GERD or IBS symptoms); Obesity due to endocrine (hypothyroidism, uncontrolled disease) disease.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization is performed by permuted block randomization (block size: 4) using RAS software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Science

Street address

Nutrition Research Center,Tabriz University of Medical Science, Tabriz

City

Tabriz

Postal code

5166614711

Approval date

2014-01-27, 1392/11/07

Ethics committee reference number

1424/4/5

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

Anthropometric measurements

Timepoint

2 Times during the study: at the beginning and end of intervention

Method of measurement

Anthropometric measurements including weight using calibrated Seca scale with a precision of 0/1 kg and a minimum of clothes in the morning, height, waist and hip circumference using a tape measure with an accuracy of 0.1 cm, and Bio Mass Index and waist-hip ratio was calculated.

2

Description

Body composition

Timepoint

2 Times during the study: at the beginning and end of each intervention month

Method of measurement

Measurement of body composition, including fat mass, fat free mass and total body water determination using Bioelectric Impedance Analyzer (BIA).

3

Description

Energy and nutrient intake

Timepoint

3 Times; at first, midst and the end of intervention

Method of measurement

3 Days food record was used and analyzed with Nutritionist 4 software

Secondary outcomes

1

Description

Fasting serum lipid profile (Low Density Lipoprotein, High Density Lipoprotein, total cholesterol, Three Glycerid)

Timepoint

Before and after intervention

Method of measurement

Enzymatic method for total cholesterol, triglyceride and High Density Lipoprotein and Friedwald's formula for Low Density Lipoprotein.c

2

Description

Hepatic Enzymes

Timepoint

Before and after intervention

Method of measurement

kits

3

Description

Determining of Uric acid, Creatinin, Bilirubin

Timepoint

Before and after intervention

Method of measurement

kits

4

Description

Serum inflammatory values (Interlukine-6, Tumor necrosis factors- α , High-sensitivity C-reactive Protein)

Timepoint

Before and after intervention

Method of measurement

High-sensitivity C-reactive Protein assess with Immunoturbidometric method and Interlukine-6, Tumor necrosis factors- α with Eliza method

5

Description

Serum levels of leptin, Ghrelin

Timepoint

Before and after intervention

Method of measurement

By Laboratory ELISA Kits

Intervention groups

1

Description

3 grams powdered dry (Origanum vulgare, Carum carvi, Trachyspermum copticum, Ruta Graveolen) as 3 capsules per day for two months

Category

Treatment - Drugs

2

Description

3 grams powdered corn starch as 3 capsules per day for 60 day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykhorræis clinic in Tabriz

Full name of responsible person

Einollah Valizadeh

Street address

Sheykhorræis clinic in Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition Research Center

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Faculty of Nutrition, Golgasht Street, Attar neishaboori Avenue

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutrition Research Center

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

Einollah valizadeh

Position

Ph.D Student

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

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Phone

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