

# 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 $\alpha$ , 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**

Determination of Uric acid, Creatinin, Bilirubin

**Timepoint**

Before and after intervention

**Method of measurement**

kits

### 4

**Description**

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

**Timepoint**

Before and after intervention

**Method of measurement**

High-sensitivity C-reactive Protein assessed with Immunoturbidometric method and Interlukine-6, Tumor necrosis factors- $\alpha$  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 Graveolens) 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 days

**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**

Nutrition Research Center, Attare Neishabouri  
Avenue, Golgasht street, Tabriz

**City**

Tabriz

**Postal code**

5166614711

**Phone**

+98 41 1335 2295

**Fax**

+98 33 52295

**Email**

evalizade@yahoo.com

**Web page address**

+98 41 1335 2295

**Fax**

+98 33 52295

**Email**

ostadrahimi@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### 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**

Nutrition Research Center, Tabriz University of  
Medical Sciences

**City**

Tabriz

**Postal code**

5166614711

**Phone**

+98 41 1335 2295

**Fax**

+98 33 52295

**Email**

evalizade@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Nutrition Research Center, Tabriz University of Medical  
Science

**Full name of responsible person**

Alireza Ostadrahimi

**Position**

Associate professor

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

Nutrition Research Center, Tabriz University of  
Medical Sciences

**City**

Tabriz

**Postal code**

5166614711

**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