

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial of weight loss programs in obese patients with majoneh etrifel saqir in comparison with placebo

Protocol summary

Summary

The study is a randomized double-blind clinical trial for comparing the effect of herbal medicine etrifel saqir with placebo. Patients with a BMI more than 30 and age range 16-60 years old will be included. The study aim is gradual weight loss that will maintain ideal body weight. In this study etrifel saqir drug (etrifel saqir composed of Terminalia chebula and Phyllanthus emblica and Terminalia bellerica; component equal weight to mixed with, almond oil or cow fat, honey Formation Concoction.) is investigated. In this clinical trial, 60 participation (30 patients receiving the drug group and 30 in the control group) according to random allocation inclusion & exclusion criteria will be recruited. for duration of three months. The medication will be used as much as one teaspoon twice a daily. The control group received placebo twice a daily. All the participants will complete the consent form. Probable side effects will be assessment during intervention, and assessment of Primary outcome are control at base line, 4 weeks, 8 weeks and 12 weeks after intervention . Primary outcome are: weight, waist and hip circumference and secondary outcome are include Fasting blood glucose, blood lipid profile and liver enzymes [CBC, FBS, 2HPP (with 100 gram Glucose), Insuline (Fasting), Cratinine, PT, aspartate aminotransferase (SGOT), Alanine Aminotransferase (SGPT), Alk Phos, Cholestrol, Triglicerid , high-density lipoprotein (HDL), low- density lipoprotein (LDL), Uric acid, hemoglobin (HGA1C)] assessment at entry and end of intervention . In addition to completing On arrival the temperament organic forms and General temperament of intervention . and Nutrition counseling and completion of a two-day food records and supply information in the entry and end of study period. And study period is three months. Concoction twice a day every time the size of a teaspoon will use. The control group received placebo twice a day can. every time the size of a teaspoon will use. In addition to completing the consent form on arrival and temperament organic forms

and general temperament and side effects completion at Before intervention, 4 weeks after intervention, 8 weeks after intervention, 12 weeks after intervention. Primary outcome measured weight and waist circumference and hip circumference and secondary outcome measured include Fasting blood glucose and blood lipid profile and liver enzymes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104206237N1**

Registration date: **2011-06-21, 1390/03/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-21, 1390/03/31

Registrant information

Name

Dr. Seyed Hamid Kamali

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 4420 6157

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Recruitment status

Recruitment complete

Funding source

Shahed university

Expected recruitment start date

2011-06-21, 1390/03/31

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of weight loss programs in obese patients with majoneh etrifel saqir in comparison with placebo

Public title

The efficacy and safety of etrifel saqir in obese patients with placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Having BMI more than 30; age between 16 to 60 years old; (Between 50 to 60 with normal ECG) inform consent signed by the patient; those who can over the next three months five times refer for take drugs and laboratory examination and Waist circumference > 102 cm (men) or > 88 cm (women)
Exclusion Criteria: Heavy Smoking (More than twenty cigarettes per daily); pregnancy; patients with coronary heart vascular disease; diabetes mellitus; 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; genetic obesity syndrome; patients treated recently with slimming drugs; patients in the last three months, have been taken thin regimes; having psychological problems (psychiatric disorder (including recent diagnosis depression, bipolar disorder, and anxiety determined by self-report during screening .(diagnosis in last three month); alcohol consumption; persons with weight loss after surgery and receiving corticosteroid or Immunosuppressive medications

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Shahed University

Street address

Keshavarz boulevard, Abdollahzadeh st., Shahed Medical University

City

Tehran

Postal code

141563511

Approval date

2011-05-31, 1390/03/10

Ethics committee reference number

112251/4

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E65

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Body Mass Index

Timepoint

Monthly

Method of measurement

Calculation of height and Weight

2**Description**

Waist circumference

Timepoint

Monthly

Method of measurement

Metric

3**Description**

Weight

Timepoint

Monthly

Method of measurement

Scale

4**Description**

Volume hip circumference

Timepoint

Before intervention, 4weeks after intervention,8 weeks after intervention, 12 weeks after intervention

Method of measurement

Metric

Secondary outcomes**1****Description**

Fasting blood glucose

Timepoint

Before intervention, 12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

2**Description**

Blood pressure

Timepoint

Monthly

Method of measurement

Blood pressure barometer

3**Description**

Serum Triglycerid

Timepoint

Before intervention, 12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

4**Description**

Serum low density lipoprotein level

Timepoint

Before intervention, 12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

5**Description**

Serum High Density Lipo protein(HDL)

Timepoint

Before intervention, 12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

6**Description**

Serum Cholestrole

Timepoint

Before intervention, 12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

7**Description**

Alanine transaminase

Timepoint

At the begining and 12th week

Method of measurement

Laboratory measurement method auto analyzer

8**Description**

Aspartate aminotransferase

Timepoint

Before intervention,12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

9**Description**

Serum Creatinin

Timepoint

Before intervention,12 weeks after intervention

Method of measurement

Laboratory measurement method auto analyzer

10**Description**

Serum Alkaline Phosphatase

Timepoint

At the begining and 12th week

Method of measurement

Laboratory measurement method auto analyzer

Intervention groups**1****Description**

Intervention group: Drug majoneh etrifel saqir composed of Phyllanthus emblica, Terminalia chebula ret, Terminaliacitrina roxb, Myrobalanus nigrae, Terminalia bellerica, a component inside almond oil and Honey. Volunteers will take a teaspoon concoction twice a day for three months.

Category

Treatment - Drugs

2**Description**

Control group: Volunteers will take a teaspoon

concoction of placebo twice a day for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Salamt clinic, Shahed University

Full name of responsible person

Dr. Seyyed Hamid Kamali

Street address

Keshavarz boulevard, Italia st., Near Mostafa Khomeini Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Heshmat

Street address

Keshavarz boulevard, Abdollahzadeh st., Shahed Medical University

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Traditonal institue

Full name of responsible person

Seyed Hamid Kamali

Position

PhD candidate of TraditionalL Medicine

Other areas of specialty/work

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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