

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the efficacy of therapeutic packages in Traditional Medicine (diet and product medicine based on Persian Traditional Medicine) with classical Medicine (diet based on Classical Medicine and Venustat) In weight loss overweight patients.

Protocol summary

Summary

1: Objectives: Comparing the efficacy of therapeutic package in Traditional Medicine (diet and product medicine based on Traditional Persian Medicine) with Classical Medicine (diet based on Classical Medicine and Venustat) in weight loss overweight patients. 2: Design: Randomized clinical trial. (single blind study) only for patients. 3: Setting and conduct: Participants are selected among female patients of Nutrition clinics in Mashhad University of Medical Sciences. After completing initial history form and Clinical examination by nutritionist and initial diagnosis of overweight is filled out a consent form by patients are referred for laboratory and anthropometric tests. 4: Participants: _The main inclusion criteria of the study are: Women between 18 and 60 years; And their Body Mass Index between 27 to 29.9 and waist circumference greater than 88 cm _The main Exclusion criteria of the study are: patients with diabetes and high blood pressure to used medicine: Chronic liver disease: Chronic renal failure: heavy smoker more than 20 cigarettes per day: Obesity caused by metabolic disorders: Familial obesity: Pregnancy: Lactation: AIDS: Hepatitis: Cancer: Obese patients referred to Obeity Clinics in the last 6 months: Patients with body composition fat and water lesser than muscle based on Bioelectrical Impedance Analyzer: A history of intolerance or allergy patients to honey, thyme, mastic , capticum and Nigella sativa. - Sample size: 100 patients. 5: Intervention: Participants will be treated in three groups: the first group with venustat and classical diet . second group with classical diet and dava balgham(product medicine based on Persian Traditional Medicine). The third group with traditional diet and dava balgham(product medicine based on Persian Traditional Medicine). Calorie consumption is equivalent in three group. Blinding is done only for patients. The treatment

period will be three months in three groups. 6: Main outcome variables: 1) Body mass index 2) Body Composition 3) Basal Metabolism Rate 4) Laboratory Parameters (CBC, FBS, LDL, HDL,Chol,TG, BUN, Cr, T3, T4, TSH, Alt, Ast, Alkp, Fe, Zn).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041927477N1**

Registration date: **2016-07-03, 1395/04/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-03, 1395/04/13

Registrant information

Name

Liely hamidnia

Name of organization / entity

School of Persian and complementary medicine of Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of therapeutic packages in Traditional Medicine (diet and product medicine based on Persian Traditional Medicine) with classical Medicine (diet based on Classical Medicine and Venustat) In weight loss overweight patients.

Public title

The effect of therapeutic models of Traditional Persian Medicine on overweight

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Age 18 to 60 years! BMI 27 to 29/9 (Kg / m2)! Waist circumference greater than 88 cm -

Exclusion criteria : Patients with diabetes and high blood pressure to used medicine! Chronic diseases of the liver! Chronic failure of kidney! Heavy smoker more than 20 cigarettes per day! Obesity caused by metabolic disorders! Familial obesity! Pregnancy! Lactation! AIDS and Hepatitis! Cancer! Obese patients referred to clinics in the last 6 months! Patients with body composition fat and water lesser than muscle based on Bioelectrical impedance analyzer! A history of intolerance or allergy to honey, thyme, mastic , capticum and Nigella sativa .

AgeFrom **77 years** old to **35 years** old**Gender**

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad, University Avenue, Building Qureshi ZIP Code: 345-91375 Phone: 5-38412081 051 051 38411538 Fax: 051 38430249 E-mail: vcresearch@mums.ac.i

City

Mashhad

Postal code**Approval date**

2016-06-20, 1395/03/31

Ethics committee reference number

IR.MUMS.REC.1395.166

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

Overweight

ICD-10 code

E65-E68

ICD-10 code description

Obesity and other hyperalimentation

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

Body max Index

Timepoint

Before intervention then every two weeks until the end of the intervention.

Method of measurement

By (Body Composition Analyzer System) model Tanita

2**Description**

Body Composition

Timepoint

Before intervention and three months after intervention

Method of measurement

Body Composition Analyzer System model tanita

3**Description**

Basal Metabolism Rate

Timepoint

Before intervention and three months after intervention

Method of measurementBy Indirect calorimetry SET[®]

Secondary outcomes

1

Description

Fast LDL

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum LDL concentration in mg/dl

2

Description

Fast HDL

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum HDL concentration in mg/dl

3

Description

Fast Blood sugar

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum sugar concentration in mg/dl

4

Description

Fast Cholesterol

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum Cholesterol concentration in mg/dl

5

Description

Fast TG

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum TG concentration in mg/dl

6

Description

Fast SGOT, SGPT, ALKP

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum SGOT .SGPT .ALKP concentration in unit/lit

7

Description

Thyroid hormones (T3 .T4 .TSH)

Timepoint

Before intervention and three months after intervention

Method of measurement

Serum Thyroid hormones concentration in ng/ml

8

Description

Fe serum concentration

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum Fe concentration in micg/dl

9

Description

Zn serum concentration

Timepoint

Before intervention and three months after intervention

Method of measurement

Fasting serum Zn concentration in micg/dl

Intervention groups

1

Description

First group: Control: Venustat: 120 mg cap: 3 cap per day for three months + Standard diet Classical Medicine for three months. (The calorie consumption is equivalent in three groups.)

Category

Treatment - Drugs

2

Description

Group 3: Second Intervention: Traditional Persian Medicine model: Traditional Persian Medicine diet. (The calorie consumption is equivalent in three groups.) + Dava Balgham. (Medicinal product based on zattaria Multiflora and Nigella Sativa, Mastic and Carum Capticum) 5 gr 2 per day morning fasting and night before sleep for three month. m.

Category

Treatment - Drugs

3

Description

Group 2: First Intervention: Classical Medicine diet.(The calorie consumption is equivalent in three groups) + Dava balgham (Medicinal product based on zattaria multiflora and Nigella sativa and Mastic and Carum capticum) 5 gr 2 per day morning fasting and night before sleep for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of School of Persian and Complementary
Medicine of Mashhad

Full name of responsible person

Liely Hamidnia PHD student of Traditional Persian
Medicine

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of
Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Vice chancellor for research, Mashhad University of
Medical Sciences, Daneshgah street

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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, Mashhad 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**

School of Persian and Complementary medicine of
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Position

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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