

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 , capicum 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)

##### Phone

+98 51 3855 2189

##### Email address

hamidnia1911@mums.ac.ir

#### 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 .

**Age**From **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 measurement**By Indirect calorimetry SET<sup>®</sup>

## 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 concentratoin

**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

**Street address**

East Razi street, School of Persian and  
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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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motavasselian@mums.ac.ir

**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

**Street address**

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

**City**

Mashhad

**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  
Mashhad

**Full name of responsible person**

Liely Hamidnia

**Position**

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

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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*