# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the effectiveness of hypericum perforatum with placebo in appetite control in obese and overweight individuals

### Protocol summary

**Study aim**
Comparison of the effect of Hypericum perforatum or placebo to standard therapy in reducing appetite and weight

**Design**
Phase 3 controlled clinical trials, community-based and pragmatic, parallel group, double-blind, randomized with sample size 60

**Settings and conduct**
Patients are selected among ones who refer to Chinese medicine and acupuncture clinic of Imam Reza Hospital. After reviewing the inclusion criteria, obtaining the informed consent and filling out the research checklist, the patient will be visited by a nutritionist to receive a diet and recommendations for exercise. Then, depending on the assigned group, he receives hypericum perforatum or a placebo.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: BMI 24.9 to 40; Women 18 years to premenopausal and men 18 to 60 years old Exclusion criteria: Hypothyroidism; Cushing's syndrome; cancer; liver or kidney failure; Psychiatric disorders associated with eating; Using drugs interfering with Hypericum perforatum or effective on weight and metabolism in the previous month; Allergy to hypericum perforatum

**Intervention groups**
Experimental group: Hypericum perforatum plus diet plus exercise Control group: placebo plus diet plus exercise

**Main outcome variables**
Appetite; Weight; Anthropometric measures

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20110809007265N12**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-30, 1397/04/09**
Update count: **0**

**Registration date**
2018-06-30, 1397/04/09

**Registrant information**

**Name**
Hoda Azizi

**Name of organization / entity**
Mashhad University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 51 1855 2188

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-05-26, 1397/03/05

**Expected recruitment end date**
2018-07-27, 1397/05/05

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the effectiveness of hypericum perforatum with placebo in appetite control in obese and overweight individuals

**Public title**
Effect of hypericum perforatum in obesity

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
BMI 24.9 to 39.9 Women 18 years to premenopausal and men 18 to 60 years old Consent to participate in the study History of at least one monotherapy failure
**Exclusion criteria:**
Hypothyroidism, Cushing's syndrome, cancer, liver or kidney failure Psychiatric disorders associated with eating like anorexia nervosa and hyperorexia Using drugs effective on weight and metabolism in the previous month Using drugs that interfere with Hypericum perforatum such as protease inhibitors, amiodarone, anticoagulants, cyclophosphamide, cyclosporine, monoamine oxidase inhibitors, phenytoin, tacrolimus, tamoxifen and trazodone drug Drug abuser or alcoholism Breast-feeding, pregnancy or planning a pregnancy during the next two months Pacemaker and any metal device inside the body due to the use of Bioelectrical Impedance Analyzer Disability to do recommended physical activity Allergy to hypericum perforatum
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomisation using number cards in sealed envelopes
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants, major researcher, nutritionist, questioner, data analyst
**Placebo**
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**
Qorashi building, Daneshgah Street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91357345
**Approval date**
2018-05-19, 1397/02/29
**Ethics committee reference number**
IR.MUMS.REC.1397.046

## 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**
Appetite
**Timepoint**
Before intervention, week 3, week 6
**Method of measurement**
Visual Analogue Scale

**2**

**Description**
Body weight
**Timepoint**
Before intervention, week 3, week 6
**Method of measurement**
Kilogram

**3**

**Description**
Waist to hip ratio
**Timepoint**
Before intervention, week 3, week 6
**Method of measurement**
Centimeter

## Secondary outcomes

**1**

**Description**
Insulin
**Timepoint**
Before intervention, after intervention
**Method of measurement**
IU

**2**

**Description**
Fasting Blood Sugar
**Timepoint**
Before intervention, after intervention
**Method of measurement**
Mg/dl

## Intervention groups

**1**

**Description**
Intervention group: diet + exercise + Hypericum perforatum 750 mg QID for 6 weeks (made by School of Iranian and Complementary Medicine, Mashhad)
**Category**
Treatment - Drugs

**2**

**Description**
Control group: diet + exercise + placebo
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Chinese and Complementary Medicine clinic, Imam Reza Hospital
**Full name of responsible person**
Dr. Hoda Azizi
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Chinese Medicine and acupuncture clinic, Imam Reza Hospital
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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Dr. Mohsen Tafaghodi
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Deputy for research office, Mashhad University of Medical Sciences, Daneshgah Street
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tafaghodim@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
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**Position**
Assistant Professor
**Latest degree**
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**Other areas of specialty/work**
Complementary Medicine
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Ph.D.

**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available