

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

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

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

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Design

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

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2018-05-26, 1397/03/05

Expected recruitment end date

2018-07-27, 1397/05/05

Intervention groups

Experimental group: Hypericum perforatum plus diet plus exercise Control group: placebo plus diet plus exercise

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Appetite; Weight; Anthropometric measures

Trial completion date

empty

General information

Scientific title

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

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007265N12**

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

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

Street address

Chinese Medicine and acupuncture clinic, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Deputy for research office, 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

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

Full name of responsible person

Hoda Azizi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Complementary Medicine

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MD, PhD in Acupuncture, Assistant Professor

Latest degree

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Position

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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