

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of integrative medicine (acupuncture, Hypericum perforatum and life style modification) with life style modification in appetite and weight control

Protocol summary

Study aim

To determine and compare the effect of adding acupuncture and / or Hypericum perforatum to life style modification in appetite and weight control

Design

A randomized, sham controlled, parallel group, phase III clinical trial with blinded patients, nutritionist, outcome assessor and statistician

Settings and conduct

Eighty-eight overweight or obese patients with appetite score ≤ 5 out of 10 will be randomly assigned to one of four groups to be treated for 6 weeks in the acupuncture and nutrition clinics affiliated to Mashhad University of Medical Sciences. Patients, nutritionist, outcome assessor and statistician will be blinded to study groups. acupuncturist could not be blinded in this study.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: People with BMI 24.9 to 39.9; women 18 years to premenopausal and men 18 to 60 years. Main exclusion criteria: 1- diseases affecting metabolism such as hypothyroidism 2- drugs affecting weight and metabolism or interfering with Hypericum perforatum 3- allergy to hypericum perforatum or metal

Intervention groups

1. Acupuncture + Hypericum perforatum + life style modification; 2. acupuncture + placebo + life style modification; 3. Sham acupuncture + Hypericum perforatum + life style modification; 4. sham acupuncture + placebo + life style modification

Main outcome variables

BMI; the appetite score; Nesfatin 1 level; waist circumference; hip circumference; body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201706107265N9**

Registration date: **2017-06-24, 1396/04/03**

Registration timing: **prospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **2**

Registration date

2017-06-24, 1396/04/03

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1855 2188

Email address

azizih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2019-11-01, 1398/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of integrative medicine (acupuncture, Hypericum perforatum and life style modification) with life style modification in appetite and weight control

Public title

The effect of acupuncture, hypericum perforatum and diet in appetite and weight control

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Appetite score more than 5 according to visual analogue scale Body mass index between 24.9 to 39.9 Women 18 years old to pre-menopause; men 18 to 60 years old Failure to life style modification alone "Liver qi stagnation" syndrome according to Chinese Medicine syndrome differentiation

Exclusion criteria:

Hypothyroidism, Cushing's syndrome, cancer, liver or kidney failure Using drugs effective on appetite, 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 abuse or alcoholism Breast-feeding, pregnancy or planning a pregnancy during the next two months Having pacemaker or any other metal device inside the body due to the use of electroacupuncture and Bioelectrical Impedance Analyzer disability to do recommended physical activity Allergy to Hypericum perforatum or metal Coagulation disorders History of receiving acupuncture

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using SPSS version 16 by selecting quadrants blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, the nutritionist, the outcome assessor, and the statistician will be blinded from the identity of the study groups. The acupuncturist will not be blinded. The participant blindness will be performed using sham acupuncture and placebo.

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

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Mashhad

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Razavi Khorasan

Postal code

91357345

Approval date

2017-06-06, 1396/03/16

Ethics committee reference number

IR.MUMS.REC.1396.43

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**

Plasma nesfatin-1

Timepoint

Before intervention, Sixth week

Method of measurement

Laboratory: ELISA

2**Description**

Appetite score

Timepoint

Before intervention, weeks 2, 4, 6, 24

Method of measurement

Visual Analogue Scale

3

Description

Body Mass Index

Timepoint

Before intervention, weeks 2, 6, 24

Method of measurement

Using the bioelectrical impedance analyzer; kg/m2

Secondary outcomes

1

Description

Waist circumference

Timepoint

Before intervention, weeks 2, 6, 24

Method of measurement

Using a tape measure; centimeters

2

Description

Hip circumference

Timepoint

Before intervention, weeks 2, 6, 24

Method of measurement

Using a tape measure; centimeters

3

Description

Body composition

Timepoint

Before intervention, weeks 2, 6

Method of measurement

Using the bioelectrical impedance analyzer

4

Description

Lipid profile

Timepoint

Before intervention, week 6

Method of measurement

Laboratory

5

Description

Liver enzymes

Timepoint

Before intervention, week 6

Method of measurement

Laboratory

6

Description

Blood glucose level

Timepoint

Before intervention, week 6

Method of measurement

Laboratory

7

Description

Adverse events

Timepoint

During the study period within 48 to 72 hours of incidence; week 6

Method of measurement

Study checklist

Intervention groups

1

Description

Intervention group 1: acupuncture, 3 times per week + 4 tablets of 160 mg Perforan (Goldaru company) + life style modification for 6 weeks

Category

Other

2

Description

Intervention group 2: acupuncture 3 times/week + placebo tablets+ life style modification for 6 weeks

Category

Other

3

Description

Intervention group 3: sham acupuncture, 3 times/week+ 4 tablets of 160 mg Perforan (Goldaru company) + life style modification for 6 weeks

Category

Other

4

Description

Control group: sham acupuncture, 3 times/week + placebo + life style modification for 6 weeks

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Acupuncture clinic, Imam Reza Hospital

Full name of responsible person

Dr. Hoda Azizi

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2

Recruitment center

Name of recruitment center
Nutrition clinic, Qaem Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

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
School of Traditional and Complementary Medicine
Full name of responsible person
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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Traditional and Complementary Medicine

Full name of responsible person

Dr. Monirsadat Sahebkar-khorasani

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Fax**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