

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Assessing the effects of sachet containing famous vulgaris extract, Morus Alba leaf extract, Coffee robusta extract, Magnesium citrate and chromium picolinate and weight reduction diet compared to diet alone on weight loss in obese or overweight adults

Protocol summary

Study aim

Determining the effects of sachet containing famous vulgaris extract, Morus Alba leaf extract, Coffee robusta extract, Magnesium citrate and chromium picolinate and weight reduction diet compared to diet alone on weight loss in obese or overweight adults

Design

Clinical trial with placebo control group, with parallel groups, double blinded, randomized, on 80 individuals with overweight/obesity, randomization with blocks of size 4 using software

Settings and conduct

The place of the study: Shahid Fayazbakhsh Hospital in Tehran; Population: people with overweight and obesity; type of blinding: double blinded; blinding, randomization and preparation of supplement cans will be done by a trained person outside the study until participants, researchers and analyzer remain blind until the end of the analysis. At the beginning and end of the intervention with supplement or placebo weight, height, BMI, and body composition will be measured. Participants in both groups will receive weight loss diets based intervention with supplement/placebo during the study period. Study duration will be 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI: 25-40, age: 18-65 years, and willing to participate in the study. Exclusion criteria: Using weight reduction medication, substance overuse, pregnancy or lactation, having known kidney disease, and having known heart disease

Intervention groups

Supplement group: One 5-gram sachet of supplement daily and weight reduction diet, Placebo group: One 5-g sachet of placebo and weight reduction diet for 8 weeks

Main outcome variables

weight; fat mass; fat free mass; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N28**

Registration date: **2023-08-27, 1402/06/05**

Registration timing: **prospective**

Last update: **2023-08-27, 1402/06/05**

Update count: **0**

Registration date

2023-08-27, 1402/06/05

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effects of sachet containing famous vulgaris extract, Morus Alba leaf extract, Coffee robusta extract, Magnesium citrate and chromium picolinate and weight reduction diet compared to diet alone on weight loss in obese or overweight adults

Public title

Assessing the effects of sachet containing white been extract, white burry extract, green coffee extract, Magnesium citrate and chromium picolinate and weight reduction in obese or overweight adults

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index of 25-40 age of 16-65years Willing to participate

Exclusion criteria:

Consuming weight reduction medications substance overuse Pregnancy and lactation Having known kidney disease Having known heart disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study are selected by convenience sampling method. Patients are classified according to age and gender, and each person will be placed in a group receiving supplementation or placebo using 1:1, quadruple random blocks. Quadruple blocks are randomly designed through software such as (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Assigning A or B to the supplement or placebo group will be done by someone outside the research so that the researchers remain blind. According to the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for randomly assigning patients. After each patient enters, according to the quadruple blocks prepared in the first stage, each patient is randomly assigned to group A or B. Assignment process will be done consecutively until the sampling is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double blind study. Participants, research team including principle investigator, data collectors, and outcome assessors will be blind to supplement or placebo allocation. Blinding would be performed by a third person out of study team. Allocation data would be unavailable to study team till the end of data collection and analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of National Nutrition and Food Technology Research Institute

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2023-06-12, 1402/03/22

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1402.016

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

Overweight and Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

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

Weight

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Scale

Secondary outcomes

1

Description

Fat mass

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Omron BF511 body composition scale

2

Description

Fat free mass

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Omron BF511 body composition scale

Intervention groups

1

Description

Intervention group: The duration of intervention in this clinical trial will be 8 weeks. Beside calorie restricted diet (300-500 Kcal less than calculated daily energy need) people will receive one 5 gram sachet of supplement (each sachet contains 150 mg famous vulgaris extract, 200 mg Morus Alba leaf extract, 400 mg Coffee robusta extract, 100 mg Magnesium citrate and 50 mcg chromium picolinate) (Samanic company)

Category

Treatment - Other

2

Description

Control group: The duration of intervention in this clinical trial will be 8 weeks. Beside calorie restricted diet (300-500 Kcal less than calculated daily energy need) people will receive one 5 gram-sachet of placebo contains maltodextrine (Samanic company).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fayaz Bakhsh Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Samanik Salamat Gostar Company

Full name of responsible person

Shamsali Rezazadeh

Street address

No 506-2, Naderi St, Keshavarz Blvd.

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Postal code

1416613485

Phone

+98 21 8839 5400

Email

info@samanik.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Samanik Salamat Gostar Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition
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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Study protocol, and report of the main output of the study would be available in case of researchers' reasonable request sending to principal investigator of the study 6 months after publishing the article.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

University researchers

Under which criteria data/document could be used

Have no other condition

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

Researches can email their enquiry for study protocol, and report of the main output of the study with reasonable request, 6 months after publishing the article and will receive the date in 2 weeks.

Comments