Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Determinig 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 saplement 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 Reseach Institute

Street address
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-saceht 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
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
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.
City
Tehran
Province
Tehran
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

Street address
No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City
Tehran

Province
Tehran

Postal code
4741-19395

Phone
+98 21 2235 7483

Email
soodehrazeghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Associate professor

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Phone
+98 21 2235 7483

Email
soodehrazeghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Associate professor

Latest degree
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Email
soodehrazeghi@gmail.com

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 enquery 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