Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Green Bean Coffee Extract on Anthropometric indices, Body composition, and cardiometabolic risk factors in Obese Adolescents: A double blind, placebo controlled, Randomized Clinical Trial

Protocol summary

Study aim
To determine effects of green bean coffee extract on Anthropometric indices, Body composition, and cardiometabolic risk factors in Obese Adolescents

Design
This study will employ a parallel-group, double-blind, placebo-controlled randomized clinical trial design. Participants will be allocated in a 1:1 ratio to receive either green bean coffee extract or a placebo for a duration of 8 weeks. the trial will be conducted with a superiority framework.

Settings and conduct
The study will be conducted at academic pediatric clinics, schools, and community health centers in Isfahan, Iran.

Participants/Inclusion and exclusion criteria
Adolescents aged 12-18 with obesity (BMI-for-age ≥ 95th percentile) are recruited. Exclusion criteria cover health issues, medication, and surgery history.

Intervention groups
Participants in the intervention group will receive green bean coffee extract containing 500 mg/day CGA for 8 weeks. Participants allocated to the control group will be administered a visually indistinguishable placebo composed of starch. Notably, the placebo has been rigorously formulated to mirror the intervention substance in weight, color, and odor.

Main outcome variables
Primary Outcome: The primary outcome of this study is the change in BMI z-score from baseline to 8 weeks after intervention. Secondary Outcomes: 1. Changes in anthropometric indices from baseline to 8 weeks after intervention. 2. Metabolic profiles, including lipid profile, glucose metabolism markers, and inflammatory markers from baseline to 8 weeks after intervention.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240213060993N1**
Registration date: **2024-02-18, 1402/11/29**
Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**
Update count: **0**
Registration date
2024-02-18, 1402/11/29

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-03-02, 1402/12/12
Expected recruitment end date
2024-06-09, 1403/03/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Green Bean Coffee Extract on Anthropometric indices, Body composition, and cardiometabolic risk factors in Obese Adolescents: A double blind, placebo controlled, Randomized Clinical Trial

Public title
effect of green coffee on obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adolescents aged 12-18 with obesity (BMI-for-age ≥ 95th percentile) Written informed consent from both participants and their legal guardians. Participants capable of full compliance with the study protocol and able to attend scheduled visits. Participants who have experienced a maximum of 5% body weight changes in the last three months.

Exclusion criteria:
Adolescents with a history of hypo- or hyperthyroidism, renal failure, routine coffee consumption, and taking corticosteroids Adolescents with a history of gastrointestinal disorders that may affect nutrient absorption (e.g., inflammatory bowel disease, celiac disease) History of significant medical conditions or medications that may impact body composition or metabolic markers Participation in any concurrent weight management or dietary intervention program Female adolescents who are pregnant, lactating, or planning pregnancy during the study period Sensitivity to green coffee bean extract or its components Undergoing any surgical procedure in the past year that may impact metabolism and body weight Significant psychiatric disorders affecting the patient's medication compliance Routine coffee consumption of two or more cups per day

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
A total 70 participants will randomly be divided into two groups. Random allocation will be carried out using permuted block randomization method with size of 2, 4 and 6 stratified by sex. The random sequences will be generated by “blockrand” package in R. The capsules (placebo/trial medication) will be allocated to participants via coded medicine containers of identical appearance prepared by an independent pharmacy.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure double-blinding, neither the participants nor the research staff involved in the study will be aware of the treatment assignments. The envelopes will be opened by an independent third party, not involved in the study, who will administer the assigned treatment accordingly. Blinding will be implemented for trial participants, care providers, and outcome assessors.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences, Hazar Jarib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2023-12-27, 1402/10/06

Ethics committee reference number
IR.ARI.MUI.REC.1402.250

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Change in BMI z-score

Timepoint
The change in BMI z-score from baseline (before starting the intervention) to 8 weeks after intervention

Method of measurement

Calculation of BMI by weight and height of the person (kilograms per square of height) and calculation of z score using the mean and standard deviation of the variable in the target population.

Secondary outcomes

1

Description
Changes in anthropometric indices
Timepoint
Changes in anthropometric indices from baseline to 8 weeks after intervention.
Method of measurement
Height: Measured using a stadiometer, with the participant standing barefoot, heels together, and head in the Frankfort horizontal plane. Weight: Measured using a calibrated digital scale with the participant in light clothing. Waist Circumference: Measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest. Hip Circumference: Measured around the widest portion of the buttocks, with the tape parallel to the floor. Waist-to-Hip Ratio: Calculated by dividing waist circumference by hip circumference.

2

Description
Metabolic profiles, including lipid profile, glucose metabolism markers, and insulin levels
Timepoint
Metabolic profiles, including lipid profile, glucose metabolism markers, insulin levels, and inflammatory markers from baseline to 8 weeks after intervention.
Method of measurement
Glucose Metabolism: Fasting blood samples will be collected after an overnight fast. Blood glucose levels will be measured using standard laboratory techniques (e.g., enzymatic methods, glucose oxidase assays). Lipid Profile: Fasting blood samples will be collected after an overnight fast. Lipid levels, including total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides, will be assessed using standard laboratory methods. Inflammatory Markers (e.g., CRP): Fasting blood samples will be collected after an overnight fast. Levels of inflammatory markers will be quantified using enzyme-linked immunosorbent assay (ELISA) techniques, which involve specific antibodies for each marker. Insulin levels: Fasting blood samples, obtained after an overnight fast, will be analyzed to determine insulin levels. The measurement will employ standard laboratory methods, likely utilizing immunoassay techniques to quantify the concentration of insulin in the blood.

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive green bean coffee extract containing 500 mg/day chlorogenic acid for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Participants allocated to the control group will be administered a placebo composed of starch
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Navaab Safavi Healthcare Center
Full name of responsible person
Milad Maghsoudi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Phone
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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
Esfahan 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
Esfahan University of Medical Sciences
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Position
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
The access period starts 3 months after the results are published
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
For include in systematic IPD studies
From where data/document is obtainable
Corresponding author in the published study

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

Within two weeks of correspondence by email

Comments