Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the clinical effect of administering oral drops containing cinnamon, ginger and lime juice in obese patients (phase 2A)

Protocol summary

Study aim
Investigating the clinical effect of administering oral drops containing cinnamon, ginger and lime juice in reducing weight and appetite in obese patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 70 patients. The Rand function of Excel software will be used for randomization.

Settings and conduct
The clinical trial in phase 2 will be conducted on 70 obese patients in Shariati Hospital. After signing the consent form, the appetite questionnaire was completed by the patients at the beginning and end of the treatment, and at the end of the treatment, the improvement of the patients' symptoms was scored based on the Likert scale from 0 to 10. Also, the weight of the patients is recorded and compared at the beginning and end of the study. The study is double-blind, and the participants and the researcher are blinded.

Participants/Inclusion and exclusion criteria
Age over 18 years, BMI less than 39.9 and more than 25

Intervention groups
The intervention group will consume 5 drops of cinnamon juice and 5 drops of ginger orally in half a glass of lemon juice. The control group, will consume placebo as 5 drops from two bottles of distilled water containing one drop of cinnamon and ginger essential oil poured into the lid of the bottle

Main outcome variables
the level of appetite; Weight

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160306026938N18**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date
2023-11-19, 1402/08/28

Registrant information

Name
Mahdi Vazirian

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6412 1223

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vazirian_m@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the clinical effect of administering oral drops containing cinnamon, ginger and lime juice in obese patients (phase 2A)

Public title

Investigating the effect of cinnamon, ginger and natural lemon juice in obesity.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent of the patient BMI lower than 39.9 and higher than 25 Age between 18 and 65 years

Exclusion criteria:

Suffering from incurable diseases Suffering from liver and kidney diseases Simultaneous use of slimming drugs Taking anticoagulants such as aspirin, warfarin and clopedogrel

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 70 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 35 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 70.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants and researcher are not informed about receiving either treatment or placebo capsules. Thus, the study is a double-blinded one. The subjects in this study were not either relatives or friends, thus they could not compare the impacts of receiving placebo/treatment. In addition, the appearance of the syrups and their containing package was exactly similar in both Intervention or control group and is not differentiated. Bottles are first coded non-sequentially by someone other than the researcher. All the study subjects received a good deal of information regarding the research plan and have been presented to them. After being randomized through the use of statistical software package, treatment or placebo has been provided for them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Qods street corner, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2023-05-17, 1402/02/27

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.027

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

Weight

Timepoint

The effect of the drug on the patient's weight is measured once every two weeks

Method of measurement

Weighing with scales

Secondary outcomes

1

Description

Appetite

Timepoint

once every two weeks

Method of measurement

Asking the individual - Likert scale

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
دکتر غلامرضا محمدی فارسانی
Street address
. Shariati Research and Medical Center, Jalal Al Ahmad Street, Kargar Shamali st.
City
Tehran
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Postal code
1411713135
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+98 21 8490 1000
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+98 21 8863 3039
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shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research and technology, Tehran university of medical sciences
Street address
Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz Boulevard
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Postal code
1417653761
Phone
+98 21 8163 3619
Email
rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Title and more details about the data/document

Data would be accessible in related dissertation.

When the data will become available and for how long

The onset of access starts from 2024

To whom data/document is available

All academic staff.

Under which criteria data/document could be used

The documents could be accessible in case of furthur experiments.

From where data/document is obtainable

Tehran University of Medical Sciences, Faculty of Pharmacy, Dr. Mahdi Vazirian

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

Personal request

Comments