

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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

Email address

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

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

+98 21 8863 3039

Email

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

City

Tehran

Province

Tehran

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

Street address

Pharmacognosy Lab., Second Floor, New building,
Faculty of Pharmacy, In front of Oruji Alley, 16th Azar
Ave., Enqelab Ave.

City

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Email

Vazirian_m@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

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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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

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