Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of oral soft gel containing lemon and cumin essential oil in various doses on weight in subjects with overweight and obesity

Protocol summary

Study aim
The aim of this study is to determine the effect of oral soft gel containing lemon and cumin essential oil in various doses on weight in subjects with BMI≥25.

Design
Parallel double-blind randomized controlled clinical trial.

Settings and conduct
72 subjects with overweight and obese eligible and referred to Naghavi Diet Therapy Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Subjects aged 18 - 50 years with overweight or obesity (BMI ≥ 25 kg/m2). The exclusion criteria will as follows: BMI < 25 kg/m2, subjects with hypertension, thyroid, diabetes or cardiovascular disorders, pregnancy and lactation and the use of hormonal or anti-obesity medications.

Intervention groups
Subjects will be assigned to receive either oral 25 mg soft gel containing lemon and cumin essential oil (intervention group: n=24), oral 75 mg soft gel containing lemon and cumin essential oil (intervention group: n=24) or placebo (control group: n=24).

Main outcome variables
Weight, fasting plasma glucose (FPG), serum insulin, insulin resistance, oxidative stress, lipid profiles and thyroid hormones

General information

Reason for update
Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information
IRCT registration number: **IRCT2015030812438N10**
Registration date: **2015-03-25, 1394/01/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **1**

Registration date
2015-03-25, 1394/01/05

Registrant information

Name
Mohsen Taghizadeh

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Barij Essence Company

Expected recruitment start date
2015-03-21, 1394/01/01

Expected recruitment end date
2015-03-30, 1394/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral soft gel containing lemon and cumin essential oil in various doses on weight in subjects with overweight and obesity

Public title
Effect of cumin and lemon on obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Overweight or obesity (BMI ≥ 25 kg/m2) Aged 18-50 years
Exclusion criteria:
BMI < 25 kg/m2 Hypertension Thyroid disorders Diabetes Cardiovascular disorders Pregnancy and lactation The use of hormonal or anti-obesity medications
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification for pre-intervention BMI and age subjects will be randomly divided into three groups to take either high-dose C. cyminum L. and lime supplements (n =24) or low-dose C. cyminum L. and lime supplements (n = 24) or placebo (n = 24). Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Kashan
City
Bolvare Ghotbe Ravandi, Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2015-02-28, 1393/12/09
Ethics committee reference number
93210

Health conditions studied

1

Description of health condition studied
Overweight and Obesity
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Weight
Timepoint
Baseline and End-of-trial
Method of measurement
scale

2

Description
Body Mass Index
Timepoint
Baseline and End-of-trial
Method of measurement
Calculation using formula

Secondary outcomes

1

Description
Total cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

2

Description
Insulin
Timepoint
Baseline and End-of-trial
Method of measurement

ELISA kit

3

Description
Triglycerides
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

4

Description
HDL-cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

5

Description
LDL-cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

6

Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

7

Description
Total antioxidant capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

8

Description
Fasting blood sugar
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

9

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Calculation using HOMA formula

Intervention groups

1

Description
Intervention group: Oral soft gel containing lemon and cumin essential oil, 25 mg, twice a day, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: Oral soft gel containing lemon and cumin essential oil, 75 mg, twice times a day, for 8 weeks orally
Category
Treatment - Drugs

3

Description
Control group: Placebo pearl, twice times a day, for 8 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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8715988141
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asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr.M.Taghizadeh
Position
PHD
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Barij Research Center of Medicinal Herbs
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M.Mahlouji
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Clinical Expert
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mahnaz.mahlouji@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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