Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Effect of oral soft gel containing lemon essential oil and Xenical capsule on weight in subjects with overweight and obesity

Protocol summary

Summary

Objective: The aim of this study is to determine the effect of oral soft gel containing lemon essential oil and Xenical capsule on weight in subjects with BMI≥25. Study design: parallel double-blind randomized controlled clinical trial. Inclusion and Exclusion Criteria: Subjects aged 18-50 years with overweight and obesity (BMI≥25) will be included in this study. Individuals with neoplastic, cardiovascular disorders, malabsorptive disorders, current or previous (within the last 6 months) use of hormonal and anti-obesity medications will be excluded in the study. Population and sample size: 105 subjects with overweight and obese eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected. Intervention: Subjects will be assigned to receive either oral soft gel containing lemon essential oil (intervention group: n=35), Xenical capsule (intervention group: n=35) or placebo (control group: n=35). Subjects' weight will be recorded in baseline and end-of-trial. Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles and thyroid hormones. Start and End Date of Intervention: 8 weeks (July 11, 2013-September 11, 2013). Outcomes: Weight, fasting plasma glucose (FPG), serum insulin, lipid profiles and thyroid hormones will be measured in baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306225623N9**
Registration date: **2013-06-30, 1392/04/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-06-30, 1392/04/09

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 36 1534 3570
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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Barij Essence Medicinal Plants Research Center

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2013-09-11, 1392/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral soft gel containing lemon essential oil and Xenical capsule on weight in subjects with overweight and obesity

Public title

Effect of oral soft gel containing lemon essential oil and Xenical capsule in treatment of obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Subjects aged 18-50 years; BMI≥25. Exclusion Criteria: Individuals with neoplastic; cardiovascular disorders; malabsorptive disorders; current or previous (within the last 6 months) use of hormonal; anti-obesity medications.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Postal code

Approval date
2013-03-13, 1391/12/23

Ethics committee reference number
P/29/5/1/4640

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
Fasting plasma glucose

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic

3

Description
Insulin

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa

4

Description
T3

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa

5

Description
T4

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa

6

Description
TSH

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral soft gel containing lemon essential oil, 100 mg, three times a day, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: Xenical capsule, 120 mg, three times a day, for 8 weeks orally.
Category
Treatment - Drugs

3

Description
Control group: Placebo capsule, three times a day, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Barij Essence Company
Full name of responsible person
Mohsen Taghizadeh
Street address
Barij Essence Company, Kashan
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Barij Essence Company
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutrition PhD
Other areas of specialty/work
Street address
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Person responsible for updating data

Contact
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asemi_z@kaums.ac.irasemi_r@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty