

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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 $\geq$ 25. Study design: parallel double-blind randomized controlled clinical trial. Inclusion and Exclusion Criteria: Subjects aged 18-50 years with overweight and obesity (BMI $\geq$ 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

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 $\geq$ 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 Rajaei 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

Bolvare Ghotbe Ravandi, Kashan

#### City

Kashan

#### Postal code

#### Phone

+98 36 1446 3378

#### Fax

#### Email

asemi\_z@kaums.ac.irasemi\_r@yahoo.com

#### Web page address

## Person responsible for updating data

### 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

Bolvare Ghotbe Ravandi, Kashan

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#### 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*