

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of capsule containing green tea, capsaicin and ginger extracts on weight of obese peoples

Protocol summary

Summary

This study is a randomized double blind , controlled with placebo , single- center , parallel clinical trial on 70 patients BMI>25, aged 18 to 50 who have any metabolic and effective on obesity disease and don't use nutritional supplement and not pregnant or lactating mother. Their baseline weight , BMI and metabolic profiles will be checked and devided to one of the groups received herbal capsules or placebo capsules Twice a day, each time two,for 8 weeks randomly. Patients don't change in Physical Activity and get food that cheked with standardized questionnaires . Finally the weight changes , metabolic profile , liver enzymes ,thyroid hormones , inflammatory markers and antioxidant parameters is measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122712438N15**

Registration date: **2016-01-05, 1394/10/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-05, 1394/10/15

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Barij Research Center of Medicinal Herbs

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of capsule containing green tea, capsaicin and ginger extracts on weight of obese peoples

Public title

The effect of green tea, capsaicin and ginger extracts on obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:18-50 years old.BMI>25 exclusion criteria: metabolic disorders; nutritional supplements; pregnancy; lactation; thyroid and parathyroid disease.

Age

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

Gender

Male

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 70
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomized based on table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Postal code

Approval date

2015-11-24, 1394/09/03

Ethics committee reference number

ir.kaums.rec1394.93181110

Health conditions studied

1

Description of health condition studied

obesity and over weight

ICD-10 code

E66

ICD-10 code description

Obesity

Primary outcomes

1

Description

Weight

Timepoint

Baseline and End-of-trial

Method of measurement

scale

2

Description

metabolic profile

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

3

Description

ALT,AST, ALK

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

4

Description

TAC

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

5

Description

Thyroid hormones

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention:herbal capsule manufactured by Barij essence pharmaceutical company, Twice a day, each time two. for 8 weeks

Category

Treatment - Drugs

2

Description

control:placebo capsule manufactured by Barij essence pharmaceutical company, Twice a day, each time two. for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Barij Research Center of Medicinal Herbs

Full name of responsible person

Miss L.Hejazi

Street address

Kashan Mashhad Ardehal Road, KM44

City

Kashan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

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****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghizadeh

Position

PHD

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Zatollah Asemi

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Clinical Expert

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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*