

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of cumin`s seed essential oil on body mass index, appetite situation, insulin resistance, leptin, as well as serum concentration of TNF alpha and Zinc alpha 2 glycoprotein in 7-12 year-old obese and overweight children

Protocol summary

Summary

The aim of this study is to evaluate the effects of cumin extract on body mass index, appetite, insulin resistance index and serum levels of tumor necrosis factor α , zinc alpha 2 glycoprotein and lipid profile in children and adolescents with obesity. Inclusion criteria are as follows: children and adolescents aged 7-12 years old with BMI above 95th percentile for their age and gender, absence of liver, kidney, digestive, endocrine and cardiovascular diseases and acute or chronic infections, not using drugs especially those that affect obesity like metformin and herbal supplements. Exclusion criteria are as follows: unwillingness to participate or continue the intervention, necessity to use medications that influence obesity or lipid and carbohydrate metabolism, affected by diabetes, thyroid disorders or other endocrine, digestive or kidney disorders, appearance of incompatibility or allergy to cumin extract. Study population: 80 children and adolescents aged 7-12 years old which are randomly assigned to two groups receiving either cumin extract or placebo each group containing 40 subjects. Intervention consists of cumin extract prescribed as pearl capsules produced by Barij Essence Co. (Iran), two capsules each day (1 capsule before lunch and 1 capsule before dinner) for two months. Placebo is prescribed simultaneously.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092624198N1**
Registration date: **2017-06-07, 1396/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Research Institute,
Tehran University of Medical Sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of cumin`s seed essential oil on body mass index, appetite situation, insulin resistance, leptin, as well as serum concentration of TNF alpha and Zinc alpha 2 glycoprotein in 7-12 year-old obese and overweight children

Public title

Evaluation Of the effect of cumin`s seed essential oil on Obese children by assessing biochemical biomarkers as well as evaluation of body mass index.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1- healthy children without any history of liver disease, 2- No sign and symptoms of hypothyroidism, Cushing syndrome , diabetes 3- No sign of hypertension Exclusion criteria 1-children who show higher level of hepatic enzymes in the first laboratory evaluation.(before starting intervention) 2-children who consume glucose regulator medicine such as Glucophage or metformin. 3-children who intake any medicine which may have any interference on appetite or obesity trend such as Hydrocortisone.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Shahid Sadoughi University Of Medical Sciences

Street address

Bahonar Square Yazd. IRAN

City

Yazd

Postal code

Approval date

2015-10-21, 1394/07/29

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.197

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

BMI

Timepoint

before intervention, two months after intervention

Method of measurement

weight in kg / height in meters squared

2

Description

fasting blood sugar

Timepoint

before intervention, two months after intervention

Method of measurement

glucose oxidase colorimetry

3

Description

SGOT

Timepoint

before intervention,one month after intervention, two months after intervention

Method of measurement

colorimetry

4

Description

SGPT

Timepoint

before intervention,one month after intervention, two months after intervention

Method of measurement

colorimetry

5

Description

Insulin

Timepoint

before intervention, two months after intervention

Method of measurement

ELISA

6

Description

TNF alpha
Timepoint
before intervention, two months after intervention
Method of measurement
ELISA

7

Description
Zinc Alpha 2 Glycoprotein
Timepoint
before intervention, two months after intervention
Method of measurement
ELISA

8

Description
HOMA-IR
Timepoint
before intervention, two months after intervention
Method of measurement
calculation

9

Description
leptin
Timepoint
before intervention, two months after intervention
Method of measurement
ELISA

10

Description
Total Cholesterol
Timepoint
before intervention, two months after intervention
Method of measurement
colorimetry

11

Description
TG
Timepoint
before intervention, two months after intervention
Method of measurement
colorimetri

12

Description
LDL
Timepoint
before intervention, two months after intervention
Method of measurement
colorimetry

13

Description
HDL

Timepoint
before intervention, two months after intervention
Method of measurement
colorimetry

14

Description
Appetite
Timepoint
before intervention, one month after intervention, two months after intervention
Method of measurement
CEBQ questionnaire

Secondary outcomes

1

Description
Creatinin
Timepoint
before intervention and 2 months after intervention
Method of measurement
colorimetry

2

Description
complete blood count
Timepoint
before intervention and 2 months after intervention
Method of measurement
microscopy

Intervention groups

1

Description
cumin` s seed essential oil orally administered as soft gel capsules twice daily (before lunch and before dinner) 2 months duration
Category
Treatment - Drugs

2

Description
placebo similar to the cumin seed oil capsule in shape and color orally administered twice daily before lunch and dinner two months duration
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Metabolic Disorders Research Center, Endocrinology

& Metabolism Research Institute

Full name of responsible person

Dr. Maryam Razzaghy Azar

Street address

5th floor, Shahrivar St., Diabetes and Metabolism
Clinic, North Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

Full name of responsible person

Dr. Neda Mehrdad

Street address

5th floor, Shariati Hospital, North Kargar St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Endocrinology and Metabolism Research Institute

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

Obesity Prevention and Treatment Research Center,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Ziadloo

Position

MSc

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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