

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of curcumin supplementation on anthropometric indices, glycemic indices, inflammatory markers, oxidative stress markers and chemerin in healthy overweight/obese female students

Protocol summary

Study aim

To determine the effect of curcumin supplementation on anthropometric indices, glycemic indices, inflammatory markers, oxidative stress markers and chemerin in healthy overweight/obese female students

Design

In this study, 60 overweight/obese students which have documents in pediatric heart research center will be chosen based on inclusion criteria of the study. participants will be randomly assigned to intervention or placebo group.

Settings and conduct

This study will be performed in pediatric heart research center. The researchers, participants and statistical analyzer will be unaware of assigned treatments.

Participants/Inclusion and exclusion criteria

overweight or obese girls (BMI percentile ≥ 85 for age), age 13-18 years old, having menstrual cycles far at least 6 months, not consuming any drugs including drugs that could affect on lipid and carbohydrate metabolism such as statins and metformin, hormone therapy drugs, multivitamin-minerals, corticosteroids and nonsteroidal anti-inflammatory drugs no history of chronic diseases including diabetes, hypo- and hyperthyroidism, liver or renal diseases, cardiovascular diseases, polycystic ovary syndrome

Intervention groups

curcumin and placebo In curcumin group, subjects will consume 500 milligram curcumin capsules for 10 week. In placebo group, subjects will consume placebo capsules which are completely similar to the main intervention. A weigh maintenance or mild weight loss diet will be prescribe for subjects based on their body mass index percentile for two intervention and placebo group.

Main outcome variables

Anthropometric indices, glycemic indices

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20171107037302N1**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3434 3834

Email address

s.sarafbank@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-09, 1396/07/17

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin supplementation on anthropometric indices, glycemic indices, inflammatory markers, oxidative stress markers and chemerin in healthy overweight/obese female students

Public title

curcumin supplementation in overweight/obese female students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

overweight or obese girls (BMI percentile ≥ 85 for age), age 13-18 years old, having menstrual cycles for at least 6 months

Exclusion criteria:

not consuming any drugs including drugs that could affect on lipid and carbohydrate metabolism such as statins and metformin, hormone therapy drugs, multivitamin-minerals, corticosteroids and nonsteroidal anti-inflammatory drugs no history of chronic diseases including diabetes, hypo- and hyperthyroidism, liver or renal diseases, cardiovascular diseases, polycystic ovary syndrome

Age

From **13 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

students will be matched for BMI percentile. By using Stratified Blocked Randomization method, students will be assigned to intervention or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, students will not be aware of type of received intervention. Furthermore, before the beginning of intervention, curcumin supplements and their placebo which are completely similar to each other will be coded to A and B by a third person rather than main researcher to keep blindness of study. The statistical analyzer will also be unaware of the allocation of treatments

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.MUI.REC.1396.3.160

Health conditions studied

1

Description of health condition studied

overweight and obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

weight

Timepoint

At the beginning of study- week 10

Method of measurement

Seca scale

2

Description

height

Timepoint

At the beginning of study- week 10

Method of measurement

Strip meter

3

Description

waist circumference

Timepoint

At the beginning of study- week 10

Method of measurement

Strip meter

4

Description

hip circumference

Timepoint

At the beginning of study- week 10

Method of measurement

Strip meter

5

Description

Body mass index

Timepoint

At the beginning of study- week 10

Method of measurement

formula

6

Description

Fasting blood sugar

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

7

Description

fasting Insulin

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

8

Description

Homeostatic model assessment of insulin resistance

Timepoint

At the beginning of study- week 10

Method of measurement

formula

Secondary outcomes

1

Description

C-reactive protein

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

2

Description

Interleukin 6

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

3

Description

Chemerin

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

4

Description

Total Antioxidant Capacity

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

5

Description

Malondialdehyde

Timepoint

At the beginning of study- week 10

Method of measurement

biochemical assessment

Intervention groups

1

Description

Intervention group: Subjects in intervention group will receive 500 milligram curcumin supplements (1 per day) for 10 week. The curcumin supplements will provide from Karen pharmaceutical and dietary supplements company, Tehran, Iran. Based on body mass index percentile, subjects will receive a weigh maintenance or a mild weight loss diet (maximum half a kilogram per month).

Category

Treatment - Other

2

Description

Control group: Subjects in control group will receive placebo (1 per day) for 10 week. The placebo will provide from Karen pharmaceutical and dietary supplements company, Tehran, Iran. The placebo will completely similar in appearance with curcumin supplements. Based on body mass index percentile, subjects will receive a weigh maintenance or a mild weight loss diet (maximum half a kilogram per month).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Heart Research Center

Full name of responsible person

Mohammadreza Sabri

Street address

Salman-e-Farsi street

City

Isfahan

Province

Isfahan

Postal code

81465-1148

Phone

+98 31 3611 5212

Email

pediatric.cardiovascular@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Masour Alavi

Street address

Hezar jarib street, Isfahan University of Medical sciences

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81746-73461

Phone

+98 31 3792 3154

Email

am.alavi@nutr.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mozhgan Nourian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar jarib street, Isfahan University of Medical Sciences, Nutrition and Food Sciences School

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Phone

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Email

Nourian@hlth.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mozhgan Nourian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sahar Saraf-Bank

Position

PhD student of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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saraf2shr@yahoo.com

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