Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 menstural 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 menstural cycles far 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
Isfehan

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
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Isfehan
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
City
Isfahan
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Isfehan
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Assistant Professor
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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