Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the adjactive effect of anti-inflammatory diet and ginger extract on liver fat grade, anthropometric and biochemical indices in 8-11 years obese children with non-alcoholic fatty liver

Protocol summary

Study aim

Evaluation of the adjactive effect of anti-inflammatory diet and ginger extract on liver fat grade, anthropometric and biochemical indices in 8-11 years obese children with non-alcoholic fatty liver.

Design

This study was conducted in a clinical trial with a blinded double-blind, 164 obese children aged 11-8 years with fatty liver who will be randomly assigned to the control and intervention groups.

Settings and conduct

This study will be performed on 164 obese children aged 10-8 years with fatty liver In Mohammad Kermanshahi Hospital in 12 weeks. After explaining the objectives of the study and obtaining conscious consent, the subjects were evaluated for liver fat status, anthropometric and biochemical indicators. Liver fat will be measured by ultrasound, biochemical indicators and lipid profiles will be measured by blood test. Then individuals will be referred to control and intervention groups. Intervention group 1 Recommendation for Anti-Inflammatory Diet, Intervention group 2 includes daily consumption of 1 gram of ginger in capsules and in Group 3 includes following the anti-inflammatory diet with consumption of 1 g of ginger in form of capsules. In this study, the control group receives 1 gram of starch daily as a placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group of 8-10 years, lack of conditions such as diabetes, endocrine diseases and diseases of the cardiovascular system. Exclusion criteria: Professional sports and lack of supplements and vitamins.

Intervention groups

Intervention 1 recommending an anti-inflammatory diet, Intervention 2 includes daily consumption of 1 gram of ginger in capsules and intervention 3 will include following an anti-inflammatory diet with 1 gram of ginger in capsules. In this study, the control group receives 1 gram of starch daily as a placebo.

Main outcome variables

The degree of fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N3**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name
Mehnoosh Samadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 83 3710 2009
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mehnoosh_samadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the adjactive effect of anti-inflammatory diet and ginger extract on liver fat grade, anthropometric and biochemical indices in 8-11 years obese children with non-alcoholic fatty liver

Public title
Evaluation of the adjactive effect of anti-inflammatory diet and Ginger extract on liver fat grade
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of diabetes Lack of cardiovascular disease Lack of endocrine disease
Exclusion criteria:
Not being a professional athlete
Age
From **8 years** old to **11 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **164**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: stratified randomization First, by attending the pediatrician's office, obese children with fatty liver with inclusion criteria will be selected, and 123 of them (three groups of 41 people) will be randomly selected for the intervention group and 41 for the control group. In order to unify the distorting variables, by using stratification for important variables, the distorting variables will enter the analysis of several variables. At first, the variables are divided into two groups of girls and boys and each group is based on the amount of physical activity divided into 3 groups: low, medium and severe. After separation based on physical activity, in the next step, the samples in each group will be divided into two categories based on calorie and macronutrient intake: low and high, and finally by Simple randomization, samples will be divided into four groups of intervention and control.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researchers and participants will not be aware of the allocation of groups, and the supplements appearance will be similar in both groups. The supplemented manufacturer will encoded the supplements before delivery.During the study, the same conditions will be met, such as attending counseling sessions and how to test for all participants.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date
2020-04-18, 1399/01/30
Ethics committee reference number
IR.KUMS.REC.1399.085

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Liver fat status
Timepoint
Before the start of the study, 12 weeks after the start of the intervention
Method of measurement
Liver fat will be measured using ultrasound and biochemical indicators and lipid profile from a blood test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Recommends taking an anti-inflammatory diet
Category
Treatment - Other

2

Description
Intervention group 2:Daily consumption of 1 gram of ginger powder in capsules with no change in daily diet
Category
Treatment - Other

3

Description
Intervention group 3: Following an anti-inflammatory diet with consumption of 1 gram of ginger powder in capsules
Category
Treatment - Other

4

Description
Control group: In this study, the control group receives 1 gram of starch as a capsule daily as a placebo.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Kermanshahi Hospital
Full name of responsible person
Karam Ahmadian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
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Building No. 2, Research Council Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Mehnoosh Samadi
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Latest degree

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Other areas of specialty/work

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Trail that began to fall ill on 21th May of 2020 should have a release plan when recording its study protocol.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

No - There is not a plan to make this available