

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the adjuvant 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 adjuvant 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)

Phone

+98 83 3710 2009

Email address

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 adjuvative 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 adjuvative 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

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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

Street address

Gomrek Street, Kermanshah, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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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

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mehnoosh Samadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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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