Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

A comparative study the effect of anti-inflammatory diet and Barberry intake on liver fat accumulation, anthropometric and biochemical indices in 8-13 year obese and overweight children with non alcoholic fatty liver

Protocol summary

Study aim
Comparison of the effect of intaking anti-inflammatory diet and barberry on liver fat accumulation, anthropometric and biochemical indicators in 8-13-year-old obese and overweight children with non-alcoholic fatty liver

Design
The current study will be conducted using a randomized clinical trial method. Children with obesity and overweight with fatty liver who meet the criteria for entering the study are selected and after obtaining informed consent to participate in the study, 48 of them will be selected as available for the intervention groups.

Settings and conduct
First, by attending the pediatric endocrinologist's office located in Kermanshah, obese and overweight children with fatty liver who meet the study entry criteria are selected. 48 people will be selected as available for the intervention groups. In this study, the amount of liver fat accumulation will be measured using the ultrasound method, the amount of liver enzymes and lipid profile will be measured through blood tests.

Participants/Inclusion and exclusion criteria
En Inclusion criteria: Age group of 8-13 years, lack of conditions such as Such as diabetes and cardiovascular disease, liver, kidney, thyroid disorder. Exclusion criteria: puberty, children who are professional athletes, use of any supplements (vitamins and minerals, etc.), the presence of digestive problems.

Intervention groups
Study groups: intervention group 1 includes weight maintenance and anti-inflammatory diet along with receiving 3 grams of barberry before meal and intervention group 2 includes receiving 3 grams of barberry before meal, intervention group 3 will include weight maintenance and anti-inflammatory diet . Weight maintenance and anti-inflammatory diet containing 18% protein, 30% fat and 52% carbohydrates.

Main outcome variables
The degree of fatty liver

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181111041611N6**
Registration date: **2022-11-28, 1401/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-28, 1401/09/07**
Update count: **0**

Registration date
2022-11-28, 1401/09/07

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
2022-11-16, 1401/08/25

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study the effect of anti-inflammatory diet and Barberry intake on liver fat accumulation, anthropometric and biochemical indices in 8-13 year obese and overweight children with non alcoholic fatty liver

Public title
A Comparative study of the effect of anti-inflammatory diet and barberry intake on non-alcoholic fatty liver status of children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Placement in the age group of 8-13 years Body mass index (BMI) above the 85th percentile Lack of diabetes Lack of cardiovascular disease Lack of diabetes liver disease Lack of kidney disease Lack of diabetes thyroid disorder
Exclusion criteria:
puberty Children of professional athletes Taking any supplements (vitamins, minerals, etc.) The presence of digestive problems
Age
From **8 years** old to **13 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method will be used to ensure that exactly the same number of participants enter the groups in a consecutive but equal time interval. At first, based on the sample size, we evaluate all possible states (permutations) of block formation, so that based on the sample size (48 people), 8 blocks of six will be produced. In each block, 6 of the three groups A, B, C (group A: intake of anti-inflammatory diet, group B: intake of barberry, group C: intake of barberry and anti-inflammatory diet) will be included twice. The blocks are produced by the statistics consultant and the envelope will be used to hide the blocks. We will assign people to three groups according to the group names in the blocks. Each of the blocks is numbered and will be used, that is, if block number 1 (for example, ABCABC) is selected by lottery, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment C, the fourth patient will receive treatment A, and the fifth patient will receive treatment B. The sixth patient will take C. For the 7th patient and onward, I consider one of the previously specified blocks by random drawing again, and for assigning people to groups, we consider the sequence of this block as the same as the first block. One of the potential problems in the blocking method is the disclosure of the last allocation in each block. This problem occurs when the study uses the blocking method with fixed blocks, which is not used in this study. Rather, the blocks are randomly selected. Software and sites also generate this block random sequence, such as: www.randomization.com www.sealedenvelope.com
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
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
کرمانشاه
Province
Kermanshah
Postal code
6719851351
Approval date
2022-10-11, 1401/07/19
Ethics committee reference number
IR.KUMS.REC.1401.324

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: including weight maintenance and anti-inflammatory diet along with intaking 3 grams of barberry before meals (Weight maintenance and anti-inflammatory diet containing 18% protein, 30% fat and 52% carbohydrates, consisting of lean meats, chicken, fish, omega-3 sources, special sources of carbohydrates, colored fruits and vegetables, nuts and legumes, fresh yogurt, products It is rich in special probiotics and honey and eliminates inflammatory foods such as high-fat foods, sugar and simple sugars, fast food and processed meats (sausages, sausages, etc.))
Category
Treatment - Other

2

Description
Intervention group: It includes taking 3 grams of barberry before meals
Category
Treatment - Other

3

Description
Intervention group: including Weight maintenance and anti-inflammatory diet containing 18% protein, 30% fat and 52% carbohydrates, consisting of lean meats, chicken, fish, omega-3 sources, special sources of carbohydrates, colored fruits and vegetables, nuts and legumes, fresh yogurt, products It is rich in special probiotics and honey and eliminates inflammatory foods such as high-fat foods, sugar and simple sugars, fast food and processed meats (sausages, sausages, etc.)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Mahmoud Ghasemi, pediatric specialist - subspecialist in pediatric endocrine and metabolic disea
Full name of responsible person
Dr. Mahmoud Ghasemi
Street address
The 1st floor of Khurshid Building, in front of Shir Khurshid Hospital, Mohammad Kermanshahi, the office of Dr. Mahmoud Ghasemi, pediatric specialist - subspecialist in pediatric endocrine and metabolic diseases
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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
Street address
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?
Yes
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
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Person responsible for updating data

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No. 12, Faraz Building, 3 Gulsarkh Alley, Pasdaran Square, Bahadurbeigi Blvd
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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
There is no further information
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available