# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

## The effect of astaxanthin supplementation on cytokeratin 18 levels in children and adolescents with non-alcoholic fatty liver

### Protocol summary

**Study aim**
Determination of the effect of astaxanthin on cytokeratin 18 levels and liver enzymes

**Design**
A concealed, randomized, blinded, controlled clinical trial with a parallel group

**Settings and conduct**
Patients with non-alcoholic fatty liver referred to clinics affiliated to Isfahan University of Medical Sciences are divided into control and intervention groups. Astaxanthin tablets are given to the intervention group and a placebo is given to the control group. Patients, physicians, researchers, and drug distributors do not know which patient will given the drug or placebo

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1- Children with non alcoholic fatty liver 2- Age 5-15 years old 3-Liver enzyme elevation excess than 40 unit/lit and diagnosis of fatty liver in sonography. •Exclusion criteria: 1-Viral Hepatitis or auto immune, Diabetes, Hemochromatosis, Cirrhosis, infectious disease, hypothiroidism 2-Consumption of drugs that effect on liver enzyme during last two months 3-Alcohol consumption 4-Discontinuing the study by the patient or his/her family

**Intervention groups**
Intervention group:8 to 18 years old children with non-alcoholic fatty liver who will be received astaxanthin. Control group: 8 to 18 years old children with non-alcoholic fatty liver who received placebo.

**Main outcome variables**
Cytokeratin level 18- Alanine aminotransferase- Aspartate aminotransferase

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170628034786N3**
Registration date: **2021-04-26, 1400/02/06**
Registration timing: **prospective**

Last update: **2021-04-26, 1400/02/06**
Update count: **0**

**Registration date**
2021-04-26, 1400/02/06

**Registrant information**

**Name**
Majid Khademian

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3844 0350

**Email address**
m.khademian@med.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-07-21, 1400/04/30

**Expected recruitment end date**
2021-11-21, 1400/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of astaxanthin supplementation on cytokeratin 18 levels in children and adolescents with non-alcoholic fatty liver

**Public title**
The effect of astaxanthin supplementation on cytokeratin

18 levels

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Children with non- alcoholic fatty liver disease Age between 8-18 years old Elevation of liver enzyme more than 40 Unit/Litre Evidence of fatty liver in sonography

**Exclusion criteria:**

Diagnosis of liver disease other than NAFLD such as : Viral hepatitis,Autoimmune hepatitis, Diabetes, Hemochromatosis, Cirrhosis, Infectious disease, Hypothyroidism Consumption of drugs that effect on liver enzyme during last two months Alcohol consumption Discontinuing the study by the patient or his/her family

**Age**

From **8 years** old to **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

During random allocation, patients will be divided into two groups of interventional and placebo by permutation block method with blocks of volume 4. (Possible permutations are: AABB, ABAB, ABBA, BBAA, BABA, BAAB). Using the random permutation block method, the samples will be assigned to two groups. Random sequences are generated using R software and a randomizeR software package

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this research, patient, researcher and data analyser not know which patient receives the drug and which one receives a placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee ofIsfahan medical university

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Approval date**

2021-04-06, 1400/01/17

**Ethics committee reference number**

IR.MUI.MED.REC.1400.005

## Health conditions studied

**1**

**Description of health condition studied**

Non alcoholic fatty liver

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

## Primary outcomes

**1**

**Description**

serum level of Alanine aminotransferase

**Timepoint**

Eight weeks after treatment initiation with placebo and astaxanthin

**Method of measurement**

Quantitative measurement of liver transaminase

**2**

**Description**

serum level of Aspartate aminotransferase

**Timepoint**

Eight weeks after treatment initiation with placebo and astaxanthin

**Method of measurement**

Quantitative measurement of liver transaminase

**3**

**Description**

Serum levels of cytokeratin 18

**Timepoint**

Eight weeks after treatment initiation with placebo and astaxanthin

**Method of measurement**

Eliza method

## Secondary outcomes

### 1

**Description**
Body fat mass
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Inbody 270 body composition measuring device

### 2

**Description**
Lean body mass
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Inbody 270 body composition measuring device

### 3

**Description**
Body mass index
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Measurement of height and weight and ratio of weight to square of height

### 4

**Description**
Waist circumference
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Measurement with meters

### 5

**Description**
Hip circumference
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Measurement with meters

### 6

**Description**
Weight
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Measurement with scales

### 7

**Description**
Height
**Timepoint**
Eight weeks after treatment initiation with placebo and astaxanthin
**Method of measurement**
Measurement with meters

## Intervention groups

### 1

**Description**
Control group: The placebo will be taken once a day with lunch, which is quite similar in color and size to the main medicine
**Category**
Placebo

### 2

**Description**
Intervention group: Patients in the astaxanthin group will receive one 8 mg tablet containing astaxanthin daily with lunch for 8 weeks. Astaxanthin supplement is provided by Nature Vision company in USA. This supplement was made from the alga Haematococcus pluvialis.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Clinics affiliated to Isfahan University of Medical Sciences
**Full name of responsible person**
Majid Khademian
**Street address**
Hezar Jerib street
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8174673461
**Phone**
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khademian51@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
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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**
Esfahan University of Medical science

**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**
Majid Khademian
**Position**
Faculty member
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

After the implementation of the research, the results will be available to the scientific community.

**When the data will become available and for how long**

One Year after publication

**To whom data/document is available**

Professional Researchers in this field

**Under which criteria data/document could be used**

After communication with the corresponding author of the project, the researchers in this field can access some statistical analysis file information

**From where data/document is obtainable**

Principal Investigator Dr. Majid Khademian Isfahan University of Medical Sciences, Faculty of Medicine, Pediatric Department of Gastroenterology, khademian51@yahoo.com

**What processes are involved for a request to access data/document**

After E-Mail to the corresponding author of the project, they will be able to provide the documentation to them. khademian51@yahoo.com

**Comments**