Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

Investigating the role of vitamin E and metformin in improving children with fatty liver

Protocol summary

Summary

The aim of this study will be to determine the effect of vitamin E and metformin on improvement children with nonalcoholic fatty liver disease. Inclusion criteria will be included: body mass index above 95 percent and the risk of non-alcoholic fatty liver. Exclusion criteria will be included diabetes or pre-diabetes patients, obesity-related hereditary diseases and chronic kidney or liver disease. Statistical population of this study will be all children from 10 to 14-year-old non-diabetic obese patients with non-alcoholic fatty liver (biopsy-proven or ultrasound). Sample size will be 200 patients (in four groups). Intervention and its time will be included: the first group of patients treated with metformin at a dose of 500 mg twice a day; the second group of patients treated with vitamin E 800 IU capsule once a day; the third group of patients treated with metformin 500 mg twice daily and vitamin E 800 IU capsule once a day; the fourth group of patients treated with placebo once a day. The initial consequences of the intervention are unclear. The Primary outcome variables will be fasting blood glucose, lipid profile, body mass index, levels of fasting insulin, insulin sensitivity, alanine aminotransferase and aspartate aminotransferase.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061334514N1**
Registration date: **2017-08-03, 1396/05/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-03, 1396/05/12

Registrant information

Name

Moaz Alhaddad

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 8709

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the role of vitamin E and metformin in improving children with fatty liver

Public title

Investigating the role of vitamin E and metformin in improving fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

The aim of this study will be to determine the effect of vitamin E and metformin on improvement children with nonalcoholic fatty liver disease. Inclusion criteria include: 1-Age 8 to 14 years 2-Body mass index above 95

percent, 3-The risk of non-alcoholic fatty liver. Exclusion criteria include: 1-Patients suffering from diabetes or pre-diabetes patient 2-BMI below 95 percent 3-History of alcohol use 4-The risk of obesity-related diseases such as hereditary syndrome, Prader Willi; 5-Pathological obesity cushingoid such as syndrome, hypothyroidism, Hypo Pseudo hyperparathyroidism 6-The risk of chronic diseases such as kidney or liver cirrhosis, viral hepatitis; 7-Lack of parental consent to participate in the study.

Age
From **8 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Shahid Bahonar St.

City
Qazvin

Postal code

Approval date
2017-05-17, 1396/02/27

Ethics committee reference number
13935/20/28 ir.qums.rec.1396.88

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
fasting blood glucose

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

2

Description
lipid profile

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

3

Description
Body mass index

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

4

Description
levels of fasting insulin

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

5

Description
insulin sensitivity

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

6

Description
alanine aminotransferase

Timepoint
Before treatment and at the second and fourth month of treatment

Method of measurement
Standard protocol

7

Description
Aspartate aminotransferase
Timepoint
Before treatment and at the second and fourth month of treatment
Method of measurement
Standard protocol

Secondary outcomes

1

Description
BMI
Timepoint
11 month
Method of measurement
BMI Formula

Intervention groups

1

Description
treated with metformin
Category
Treatment - Drugs

2

Description
treated with Vit. E
Category
Treatment - Drugs

3

Description
treated with metformin + Vit. E
Category
Treatment - Drugs

4

Description
placebo-treated
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods Center
Full name of responsible person
Maaz Alhaddad
Street address
Quds Hospital, Quds Square, Shahid Beheshti St.
Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Peymani
Street address
Qazvin university of medical sciences, Shahid Bahonar St. Qazvin
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Saffari
Position
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Person responsible for scientific

inquiries

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Name of organization / entity
Qazvin University of Medical Sciences
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Maaz Alhaddad
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Person responsible for updating data

Contact
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Quds Hospital, Quds Sq., Shahid Beheshti St., Qazvin
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4595-1-34159
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty