

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

Email address

m.alhaddad@qums.ac.ir

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 Bahrar 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

Qods Hospital, Qods 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

associated prof.

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

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Maaz Alhaddad

Position

resident

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Contact

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Maaz Alhaddad

Position

General Physician

Other areas of specialty/work

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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