Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

The evaluation of the effect of vitamin E and metformin on fatty liver in obese children

Protocol summary

Summary

The main aim of this study is to investigate the effect of metformin and vitamin E on echogenisity of liver in obese children with fatty liver. 104 patients (4-18 years old) with fatty liver are recruited and randomly assigned into four equal number groups to receive metformin 500 mg bd, metformin 500 mg tds, vitamin E 400 u or vitamin E 800 u for two months. Liver sonography is performed in all patients. If the patient was not cured, we continue the intervention for two month and repeat liver sonography and changes are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021012421N1**
Registration date: **2013-05-05, 1392/02/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-05, 1392/02/15

Registrant information

Name
Kobra Shiasi arani
Name of organization / entity
Kashan University of Medical Sciences and Health Services
Country
Iran (Islamic Republic of)
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+98 31 5557 4430
Email address
shiasi_k@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of vitamin E and metformin on fatty liver in obese children

Public title

The effect of vitamin E and metformin on fat

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: presence of fatty liver. Exclusion criteria: alcoholism; another chronic disease such as viral hepatitis.

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences and Health Services

Street address

Medical college, Ghotb Ravandi boulevard

City

Kashan

Postal code

8715981151

Approval date

2012-03-13, 1390/12/23

Ethics committee reference number

4269/1529/پ

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

liver ecogenicity

Timepoint

before and 2 months after the intervention and end of intervention (four months after intervention)

Method of measurement

sonography

Secondary outcomes

1

Description

BMI

Timepoint

before and 2 months after the intervention and end of intervention (four months after intervention)

Method of measurement

balance and height messuring instruments

Intervention groups

1

Description

Metformin 500mg tab bd

Category

Treatment - Drugs

2

Description

Metformin 500mg tab tds

Category

Treatment - Drugs

3

Description

vitamin E 400 unit pearl daily

Category

Treatment - Drugs

4

Description

vitamin E 400 unit pearl bd

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Kashan University of Medical Sciences and Health Services

Full name of responsible person

Moazami Goudarzi Raziyeh

Street address

Medical college, Ghotb Ravandi boulevard

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr. Qolam Ali Hamidi

Street address

Medical college, Ghotb Ravandi boulevard

City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kashan University of Medical Sciences and Health Services
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences and Health Services
Full name of responsible person
Moazami Goudarzi Raziyeh
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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