Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of vitamin D and placebo application on sonographic, laboratory and some biochemical criteria of fatty liver in overweight and obese children aged between 12 and 18 years

Protocol summary

Summary

In this study, the effects of vitamin D and placebo on ultrasonographic and laboratory criteria for fatty liver and some biochemical parameters of blood are compared in overweight and obese children aged 12 to 18 years. The population involves schoolchildren in Birjand among whom a total of 120 will be selected by multi-stage sampling method and will be assigned into control and intervention groups via simple random method (60 in each group). Major inclusion criteria include overweight and obese children based on Centers for Disease Control and Prevention of the United States; children with fatty liver based on ultrasound criteria; and age between 12 and 18 years. Major exclusion criteria include children with underlying conditions including thyroid dysfunction, diabetes and Cushing's syndrome, as well as the chronic consumption of any drug. The study is multi-centered and in the second phase of clinical trials. The intervention group receives 50000 international unit vitamin D as pearl on a weekly basis for 12 weeks; the control group will receive placebo in the same color and dose for the period of time. Before the intervention and at the end of the 12-week intervention, a set of tests were performed for liver enzymes functions (aspartate aminotransferase, alanine aminotransferase and alkaline phosphatase), some biochemical parameters of blood (blood lipids, uric acid, albumin, insulin and fasting blood glucose), as well as complete blood count with differential, C-reactive protein, vitamin D, and liver ultrasonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082017756N23**
Registration date: **2017-08-25, 1396/06/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-25, 1396/06/03

Registrant information

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Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Birjand University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vitamin D and placebo application on sonographic, laboratory and some biochemical criteria of

fatty liver in overweight and obese children aged between 12 and 18 years

Public title
Effect of vitamin D on sonographic and laboratory and criteria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age between 12 and 18 years; children with overweight and obesity based on Centers for Disease Control and Prevention of the United States; children with fatty liver based on ultrasound criteria; vitamin D deficiency under laboratory test; willingness to collaborate in the study. Exclusion criteria: Children with background diseases including known thyroid dysfunction (hypothyroidism and hyperparathyroidism), diabetes and Cushing's syndrome; chronic use of any drug such as corticosteroids, and weight reducing and weight gain drugs; history of alcoholism and hepatitis induced by other causes (hereditary diseases, viruses, etc.); and unwillingness to continue cooperation in the study.
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
The study is double-blind; the participants and data collector(s) are uninformed of the study groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand,
Postal code
Approval date
2017-04-19, 1396/01/30
Ethics committee reference number
Ir.bums.REC.1396.13

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
C-reactive protein
Timepoint
before and after intervention
Method of measurement
Laboratory test in terms of milligram per deciliter

2

Description
Fasting blood sugar
Timepoint
before and after intervention
Method of measurement
Laboratory test in terms of milligram per deciliter

3

Description
Insulin
Timepoint
before and after intervention
Method of measurement
Laboratory test

4

Description
Aspartate Aminotransferase
Timepoint
before and after intervention
Method of measurement
Laboratory test

5

Description
Alanine Aminotransferase
Timepoint

before and after intervention
Method of measurement
Laboratory test

6

Description
Alkaline phosphatase
Timepoint
before and after intervention
Method of measurement
Laboratory test

7

Description
Uric acid
Timepoint
before and after intervention
Method of measurement
Laboratory test

8

Description
hemoglobin
Timepoint
before and after intervention
Method of measurement
Laboratory test

9

Description
Albumin
Timepoint
before and after intervention
Method of measurement
Laboratory test

10

Description
Platelet
Timepoint
before and after intervention
Method of measurement
Laboratory test

11

Description
High-density lipoprotein
Timepoint
before and after intervention
Method of measurement
Laboratory test

12

Description
low density lipoprotein
Timepoint
before and after intervention
Method of measurement
Laboratory test

13

Description
Cholesterol
Timepoint
before and after intervention
Method of measurement
Laboratory test

14

Description
triglyceride
Timepoint
before and after intervention
Method of measurement
Laboratory test

15

Description
Fatty liver
Timepoint
before and after intervention
Method of measurement
Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group (Vitamin D capsule): The intervention group receives 50000 international unit vitamin D as pearl on a weekly basis for 12 weeks.
Category
Treatment - Drugs

2

Description
Control Group (Placebo): The control group will receive placebo in the same color and dose for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr Mahia Hosseini
Street address

Pediatrics Ward, Vali-e Asr Hospital, Ghaffari St.,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery of Research and Technology, Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

Street address

Vice-chancellery of Reasearch and Technology, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellery of Research and Technology, Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr Mahia Hosseini

Position

Assistant of Pediatrics

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