

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

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

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

lr.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 Research 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

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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