

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Comparison of serum level of vitamin D in Patients with Non-alcoholic Fatty Liver Disease (NAFLD) after administration of Oral & Intramuscular Vit D

Protocol summary

Study aim

Comparison of serum level of vitamin D in Patients with Non-alcoholic Fatty Liver Disease (NAFLD) after administration of Oral & Intramuscular Vit D

Design

Two arm parallel group randomised clinical trial

Settings and conduct

Gastrointestinal Clinic of Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with non-alcoholic fatty liver (NAFLD) refer to gastrointestinal clinic of Tabriz University of Medical Sciences. Inclusion criteria included: Adolescents over 18 years of age with non-alcoholic fatty liver disease (NAFLD) based on diagnosis of gastroenterologist, evidence of fatty liver based imaging or pathology report, lack of alcohol use, absence Hereditary disease history, lack of osteatogenic drugs, vitamin D deficiency (25-hydroxyvitamin D level less than 20 ng / ml), and patient's informed consent to participate in the study. Exclusion criteria also included other low-level vitamin D diseases such as celiac disease, IBD, cystic fibrosis, short bowel syndrome, a history of thyroid and parathyroid problems, as well as recent consumption of vitamin D, viral hepatitis, and informed consent. The patient is eligible to participate in the study.

Intervention groups

One group of patients will be treated with oral vitamin D (pear vitamin D) at 50,000 units weekly for one month and then 50,000 units monthly for one month. In the second group patients will receive vitamin D of 300,000 units two units within one month.

Main outcome variables

Initial vitamin D levels Final vitamin D levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N2**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **prospective**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

mkhoshbaten@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum level of vitamin D in Patients with Non-alcoholic Fatty Liver Disease (NAFLD) after administration of Oral & Intramuscular Vit D

Public title

Oral and intramuscular administration of vitamin D in patients with nonalcoholic fatty liver

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult Patients Over 18 Years With Non-alcoholic Fatty Liver Disease (NAFLD) Based on Diagnosis of Gastroenterologist Osteatogenic drugs vitamin D deficiency (25-hydroxyvitamin D level less than 20 ng / ml), and informed patient consent to participate in the study informed patient consent to participate in the study

Exclusion criteria:

Alcohol consumption hereditary history osteogenic drugs hepatitis metabolic diseases Recent consumption of vitamin D

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into oral and muscle groups using randomized block method. Patients will be divided into two equal groups using a random number table. STATA software will be used to generate the random sequence.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht Ave, imam Reza hospital clinic, tabriz

City

tabriz

Province

East Azarbaijan

Postal code

5154751634

Approval date

2019-11-25, 1398/09/04

Ethics committee reference number

IR.TBZMED.REC.1398.882

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**

Vitamin D levels in both groups will be measured at baseline. One group of patients will be treated with oral vitamin D (pear vitamin D) at 50,000 units weekly for one month and then 50,000 units monthly for one month. In the second group, patients will receive vitamin D of 300,000 units two months apart. The level of 25-hydroxyvitamin D in both groups will be re-measured 2 months after the start of treatment. The primary outcome of the present study was the level of 25-hydroxyvitamin D levels 3 months after initiation of vitamin D treatment.

Timepoint

Vitamin D levels in both groups will be measured at baseline. It will be re-measured 2 months after the start of treatment.

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group : Patients in this group will receive injection muscle vitamin D as 300,000,000 units every month for two month.

Category

Other

2

Description

Control group: In this group, patients will be treated with oral vitamin D (pear vitamin D) 50,000 units weekly for one month and then 50,000 units monthly for one month.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

imam Reza hospital

Full name of responsible person

Manouchehr Khoshbaten

Street address

Golgasht Ave, imam reza hospital clinic, tabriz

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Email

mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmodpour

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Golgasht Ave, imam reza hospital clinic

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Email

a.mahmoodpour@gmail.com

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, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Manouchehr Khoshbaten

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available