

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154751637

##### Phone

+98 41 3337 2088

##### 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 Mahmoodpour

##### Street address

Golgasht Ave, imam reza hospital clinic

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154751637

##### Phone

+98 41 3337 2084

##### 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

##### Street address

Gplgasht Ave, imam reza hospital

##### City

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Manouchehr Khoshbaten

##### Position

professor

##### Latest degree

Subspecialist

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

Tabriz University of Medical Sciences

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**Province**

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**Postal code**

5154751637

**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