Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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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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
Street address
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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
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Person responsible for updating data

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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