

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The relationship between vitamin D treatment and reduction of liver involvement severity in patients with non-alcoholic liver

#### Protocol summary

##### Study aim

determine effect of vitamin D treatment on liver involvement severity in patients suffered from non alcoholic fatty liver

##### Design

Clinical trials without control group, not blinded and not randomised

##### Settings and conduct

This study will be conducted on patients with non-alcoholic fatty liver disease who are referred to the Center for Applied Scientific Research and after receiving their consent. The intervention group will receive 50000mg vitamin D for 4 months on an weekly basis. Patients will be screened for ultrasound examination of fatty liver gradients. Measurement of the level of liver enzymes will be taken part in the Danesh lab and performance of ultrasound in the Tabesh imaging center.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who have been diagnosed with non-alcohol fatty liver with vitamin D deficiency  
Exclusion criteria: alcohol consumption history; cancers; melitus diabetics; thyroid disease; chronic kidney disease

##### Intervention groups

the case group will receive 50000mg Vitamin D weekly whereas the control group will receive nothing.

##### Main outcome variables

Liver Enzymes (AST; ALT); ultrasound grade

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150802023468N6**  
Registration date: **2019-10-28, 1398/08/06**  
Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

##### Registration date

2019-10-28, 1398/08/06

##### Registrant information

###### Name

Nazli Rabienejad

###### Name of organization / entity

Hamadan university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 1059

###### Email address

n.rabinezhad@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The relationship between vitamin D treatment and reduction of liver involvement severity in patients with non-alcoholic liver

##### Public title

relationship between vitamin D treatment with liver involvement severity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

vitamin D deficiency patients suffered from non-alcoholic fatty liver disease

**Exclusion criteria:**

alcohol consumption history positive HBS Ag auto immunize hepatitis cancers melitus diabetics thyroid disease chronic kidney disease

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**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**

Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2019-01-21, 1397/11/01

**Ethics committee reference number**

IR.TBZMED.REC.1397.871

**Health conditions studied****1****Description of health condition studied**

non alcoholic fatty liver disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**Primary outcomes****1****Description**

Grade ultrasound

**Timepoint**

At the beginning of the study, 4 months

**Method of measurement**

Sonography

**2****Description**

vitamin D

**Timepoint**

At the beginning of the study, 4 months

**Method of measurement**

blood test

**Secondary outcomes**

empty

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

Intervention group: vitamin D 50000 weekly for 4 months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Reza Teaching Hospital of Tabriz

**Full name of responsible person**

Manuchehr khoshbaten MD

**Street address**

Golgasht street, Tabriz

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

59-3347054

**Phone**

+98 41 3334 7054

**Email**

info@imamreza.tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Ata Mahmoudpour

**Street address**

Golgasht street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3337 7459

**Email**

medfac@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Niloorabi Rabienejad

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Golgasht street, Tabriz

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5166414766

**Phone**

+98 41 3382 2082

**Email**

niloorabi@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Niloorabi Rabienejad

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Golgasht street, Tabriz

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5166414766

**Phone**

+98 41 3382 2082

**Email**

niloorabi@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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Niloorabi Rabienejad

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student

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Medical doctor

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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**

Undecided - It is not yet known if there will be 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