

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

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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

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tabriz

Province

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Postal code

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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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