Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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
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Nazli Rabienejad
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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
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
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59-3347054
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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
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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
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Niloofar Rabienejad
Position
Student
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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

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