Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Investigation of the effect of vitamin D supplementation on improvement of liver function test in type 2 diabetic patients who have both vitamin D deficiency and nonalcoholic fatty liver disease

Protocol summary

Summary

This clinical trial study is designed to verify the hypothesis that providing vitamin D supplement to type 2 diabetic patients with nonalcoholic fatty liver disease and vitamin D deficiency might improve liver function test. 115 diabetic patients will be evaluated for fatty liver change (by ultrasound) and serum biochemical markers (liver function test (LFT), fasting blood sugar , HbA1c, lipid profile, and vitamin D level). patients who are consuming drugs that have the potential to cause fatty liver will be excluded. Those patients who have both nonalcoholic fatty liver disease and vitamin D deficiency will be provided with 50000 IU vitamin D/week orally for 12 weeks. One week after the last does the same biochemical markers will be evaluated and compared with those before treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020816528N1**
Registration date: **2014-05-03, 1393/02/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

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Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2014-04-29, 1393/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of vitamin D supplementation on improvement of liver function test in type 2 diabetic patients who have both vitamin D deficiency and nonalcoholic fatty liver disease

Public title

Effect of vitamin D supplementation on nonalcoholic fatty liver disease in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known case of type II diabetes who have been treated for at least 6 months exclusion criteria: positive history of alcohol use; positive history of hepatitis B or C; chronic liver or renal disease; consumption of drugs known to cause fatty liver change (such as estrogen, metotrexate, Tamoxifen, Tetracyclin, Oral contraceptive pills, sodium valporate); pregnancy or

lactation; positive history of thyroid disease

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **115**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord university of medical sciences

Street address
Shahrekord university of medical sciences, Shahrekord, Iran

City
Sharekord

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
1071

Health conditions studied

1

Description of health condition studied
nonalcoholic fatty liver

ICD-10 code
k76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
liver enzymes(AST, ALT, GGT)

Timepoint
at the begining of the study and 1 week after the last dose of vitamin D supplement

Method of measurement
ELISA

Secondary outcomes

1

Description
Lipid profile (cholesterol, HDL, LDL, TG)

Timepoint
at the begining of the study and 1 week after the last dose of vitamin D supplement

Method of measurement
spectrophotometry

2

Description
HbA1C

Timepoint
at the begining of the study and 1 week after the last dose of vitamin D supplement

Method of measurement
HPLC

3

Description
(fasting blood sugar) FBS

Timepoint
at the begining of the study and 1 week after the last dose of vitamin D supplement

Method of measurement
spectrophotometry

Intervention groups

1

Description
In the intervention group vitamin D pearl (50000 IU) is administered orally one pearl per week for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali Clinic

Full name of responsible person

Street address

City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Mitra Saadat
Street address
Shahrekord University of Medical Sciences
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty