

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Name

Alireza Alireza

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 beginning 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 beginning of the study and 1 week after the last dose of vitamin D supplement

Method of measurement

spectrophotometry

2

Description

HbA1C

Timepoint

at the beginning 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 beginning 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

Contact

Name of organization / entity

Shahrekord university of medical sciences,
Shahrekord, Iran

Full name of responsible person

Alireza Dabbaghmanesh

Position

Internist (resident)

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Seied Mahmood Mirhoseini

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endocranologist

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Other areas of specialty/work

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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