

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of low caloric diet with and without vitamin D supplementation on trends of disease in non alcoholic fatty liver

Protocol summary

Summary

As a result of high prevalence of hypovitaminosis D in the non alcoholic fatty liver patients we design a randomized double blind controlled trial in order to understand the relation of vitamin D with nonalcoholic fatty liver. at first and the end of the trial biochemical tests like (Fasting blood sugar, Total cholesterol, Triglyceride, AST, ALT, ALP, LDL, HDL, Bilirubin, OH-25 vitamin D, calcium, phosphor) and anthropometric parameters like (Weight, Height & Waist circumference) will assess. also ultra sonography will assess at the beginning and in the end of the trial. Inclusion criteria: BMI>25 OH-25 vitamin D< 20 ngr/ml SGPT>40 mgr/dl a grade of fatty liver Exclusion criteria: liver disease kidney disease using spatial kind drug patients fulfilling criteria will be randomized to receive an intervention or to be in the control group. intervention group use low caloric diet and 50000 IU of vitamin D weekly and control group will use only low caloric diet. patients will follow up for 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091310826N1**

Registration date: **2013-02-02, 1391/11/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-02, 1391/11/14

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoghi Medical University of Yazd

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low caloric diet with and without vitamin D supplementation on trends of disease in non alcoholic fatty liver

Public title

Effect of low caloric diet with and without vitamin D supplementation in non alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 25 to 65 years; Body mass index ≥ 25 ; OH 25 Vitamin D < 50 nmol/lit or 20 ng/ml; increase SGPT level more than 40 mgr/dl; distinction of the grade of fatty liver by sonography and understanding by doctor. Exclusion criteria: liver disease like hepatitis; kidney disease; use low caloric diet or drugs for decrease weight in 6 month ago; lactation;

gestation; use of steroid drugs; tamoxifen, prexilin, metotroxat, statin drugs; use of vitamin E & D 3 month ago; using alcoholic drinks; also patients that have weigh loss less than 5 percent of body or patients that without using 80 percent of vitamin D supplements will exclude from study.

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Science

Street address

Yazd, Imam Hosein Square

City

Yazd

Postal code

Approval date

2012-11-19, 1391/08/29

Ethics committee reference number

17/1/117118/پ

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver

ICD-10 code

k76.0

ICD-10 code description

Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description

SGPT

Timepoint

befor & after intervention

Method of measurement

mgr/dl, by blood sampling

2

Description

liver and bile duct supersonic graphy

Timepoint

before & after intervention

Method of measurement

radiologic picture

3

Description

OH 25 vitamin D

Timepoint

before & after intervention

Method of measurement

ngr/dl, blood sample

4

Description

BMI

Timepoint

before & after intervention

Method of measurement

kgr/m2,

Secondary outcomes

1

Description

waist circumfrence

Timepoint

before & after intervention

Method of measurement

cm, meter

2

Description

SGOT

Timepoint

before & after intervention

Method of measurement

mgr/dl, blood sample

3

Description

billirobin

Timepoint

before & after intervention
Method of measurement
mgr/dl,blood sample

4

Description
Alkaline phosphatase
Timepoint
before & after intervention
Method of measurement
IU, blood sample

5

Description
Calcium
Timepoint
before & after intervention
Method of measurement
mgr/dl,blood sample

6

Description
Phosphorus
Timepoint
before & after intervention
Method of measurement
mgr/dl, blood sample

7

Description
Fasting Blood Sugar
Timepoint
before & after intervention
Method of measurement
mgr/dl

8

Description
Triglyceride
Timepoint
Before & after intervention
Method of measurement
mgr/dl,blood sample

9

Description
Total cholesterol
Timepoint
before & after intervention
Method of measurement
mgr/dl,blood sample

10

Description
HDL
Timepoint
before & after intervention

Method of measurement
mgr/dl,blood sample

11

Description
LDL cholesterol
Timepoint
before & after intervention
Method of measurement
mgr/dl,blood sample

12

Description
weight
Timepoint
before & after intervention
Method of measurement
digital scale

13

Description
height
Timepoint
before & after intervention
Method of measurement
stadiometer,m

Intervention groups

1

Description
intervention group: using low caloric diet (kilo caloric/ body weight) - 500. 20% protein, 52% carbohydrate, 28% fat.also they use 50000 IU vitamin D weekly for 3 month.
Category
Treatment - Drugs

2

Description
control group: using low caloric diet (kilo caloric/ body weight) - 500. 20% protein, 52% carbohydrate, 28% fat.also they use placebo of vitamin D weekly for 3 month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ARA Health clinic
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research services of shahid sadoughi university

Full name of responsible person

Dr. Hassan Mozafari

Street address

Yazd, bahonar square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research services of shahid sadoughi university

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of nutrition, School of public health,
Shahid Sadoughi University

Full name of responsible person

Azade Najarzadeh

Position

PhD, Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University

Full name of responsible person

Narges Jani

Position

Msc student, Department of nutrition, School of public
health, Shahid Sadoughi University

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