

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of Vitamin E and Pioglitazone in patients with non-alcoholic fatty liver disease in Marvdasht Hospital

Protocol summary

Summary

The aim of this study is to determine effectiveness of vitamin E and Pioglitazone in improving some biochemical markers in NAFLD. The study will be designed as a randomized double-blinded, placebo-controlled trial. We will be recruited consecutively NAFLD patients aged between 18 to 60 years from outpatient clinic of Shahid Mottahari hospital (Marvdasht, Iran) during 6 months' period. Inclusion criteria included patients with NAFLD confirmed by performing liver sonography and increased levels of liver enzymes AST and ALT. Exclusion criteria included a history of alcohol consumption, diabetes, chronic liver disease, use of drugs such as statin, fibrate. The patients will be randomly allocated into three study groups; group A subjects will be treated with only lifestyle modification and placebo. Group B subjects will be administered with lifestyle modification and Vitamin E 400 IU/day. Group C subjects will be administered with lifestyle modification and pioglitazone 15 mg/day. Treatment courses will be considered for three months. The primary outcome is biomarker changes of liver function test at initial and 3 months after intervention. In addition, we will be considered BMI and waist circumference as secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705016312N4**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Amir Anushiravani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1634 4292

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2017-10-30, 1396/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin E and Pioglitazone in patients with non-alcoholic fatty liver disease in Marvdasht Hospital

Public title

Effect of Vitamin E and Pioglitazone in patients with non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with NAFLD confirmed by performing liver sonography and increased levels of liver enzymes AST and ALT. Exclusion Criteria: History of

alcohol consumption; diabetes; chronic liver disease; use of drugs such as statin, fibrate.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.SUMS.MED.REC.1396.12

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K75.8

ICD-10 code description

Nonalcoholic steatohepatitis

Primary outcomes

1

Description

liver function test

Timepoint

Before intervention - 3 months after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before intervention - 3 months after intervention

Method of measurement

By BMI Formula

Intervention groups

1

Description

Intervention group: lifestyle modification and Vitamin E 400IU/day for 3 months

Category

Treatment - Drugs

2

Description

Intervention group: lifestyle modification and pioglitazone 15 mg/day for 3 months

Category

Treatment - Drugs

3

Description

Control group: lifestyle modification and placebo for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital and Clinic

Full name of responsible person

Amir Anushiravani

Street address

Motahari hospital and clinic, Moalem Square

City

Marvdasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University Of Medical Science

Full name of responsible person

Dr Seyed Baser Hashemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University Of Medical Science

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

International branch_Shiraz University of Medical Sciences

Full name of responsible person

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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