Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 Motahari 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

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Name of organization / entity
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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

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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