Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of pioglitazone on the improvement of non-alcoholic fatty liver in obese patients

Protocol summary

Study aim
The effect of pioglitazone on the improvement of non-alcoholic fatty liver in obese patients
Design
Clinical trial with control group with parallel groups, phase 2-3 on 44 patients
Settings and conduct
This study is performed in Al-Zahra Hospital in Isfahan. Patients in the intervention group will be treated with pioglitazone tablets and their degree of non-alcoholic fatty liver will be measured before and after the interventions.
Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 and 65 years, candidate for bariatric surgery, non-alcoholic fatty liver disease grade 3, satisfaction with inclusion in the study
Exclusion criteria: daily consumption of more than 40 grams and 20 grams of alcohol for men and women, respectively, having other liver diseases, liver cancer, taking hepatotoxic drugs
Intervention groups
Intervention group: Patients in this group are examined for the degree of fatty liver and then for 4 months, in addition to dietary recommendations, will receive pioglitazone 15 mg tablets 2 times a day. After the interventions, the degree of fatty liver will be measured again. Control group: Patients in this group will be examined for the degree of fatty liver and will only receive routine dietary recommendations and after 4 months their fatty liver will be measured again.
Main outcome variables
Fatty liver grade

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210614051574N3**
Registration date: **2021-08-07, 1400/05/16**
Registration timing: **prospective**

Last update: **2021-08-07, 1400/05/16**
Update count: **0**
Registration date
2021-08-07, 1400/05/16

Registrant information
Name
Ghasem Mohammadsharifi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-04, 1400/06/13
Expected recruitment end date
2021-10-05, 1400/07/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pioglitazone on the improvement of non-alcoholic fatty liver in obese patients

Public title
Pioglitazone and non-alcoholic fatty liver
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years Candidate for bariatric surgery Non-alcoholic fatty liver disease grade 3 Satisfaction with inclusion in the study

Exclusion criteria:

Daily consumption of more than 40 grams and 20 grams of alcohol for men and women, respectively Having other liver diseases Liver cancer Taking hepatotoxic drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MUI.MED.REC.1398.053

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Fatty liver grade

Timepoint

Before and 4 months after treatment

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are examined for the degree of fatty liver and then for 4 months, in addition to dietary recommendations, will receive pioglitazone 15 mg tablets 2 times a day. After the interventions, the degree of fatty liver will be measured again.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will be examined for the degree of fatty liver and will only receive routine dietary recommendations and after 4 months their fatty liver will be measured again.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Masoud Sayadi

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan
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Email
haghjoo.sh@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Sayadi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments