

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3729 4005

###### Email address

mohammadsharifi.ghasem@gmail.com

##### 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

Isfahan

##### 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

##### City

Isfahan

##### Province

Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 0042  
**Email**  
parsa.alinezhad85@gmail.com

## 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  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673118  
**Phone**  
+98 31 3668 0048  
**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**  
General Surgery

#### Street address

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Masoud Sayadi  
**Position**  
Assistant professor  
**Latest degree**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Masoud Sayadi  
**Position**  
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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**