

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparing the effects of doses empagliflozin 10 mg and 25 mg on anthropometric index and liver enzymes in patients with non alcoholic fatty liver (NAFLD)

Protocol summary

Study aim

Comparing the effects of doses empagliflozin 10 mg and 25 mg on anthropometric index and liver enzymes in patients with non alcoholic fatty liver (NAFLD)

Design

A clinical trial based, pragmatic, parallel-group, randomized, unblinded, phase 2 controlled clinical trial on 116 patients.

Settings and conduct

It is a clinical trial study and will be conducted for three months in clinics in Zanjan in 1404. Patients with non-alcoholic fatty liver disease will be divided into two groups. The weight-stabilizing diet will be set for patients and it is recommended that they walk at a moderate pace for a maximum of half an hour daily. Anthropometric and paraclinical indices will be recorded at the beginning and end of the study. Also, the FIB4 index will be calculated using the formula..

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with non alcoholic fatty liver (NAFLD) referred to Gastroenterology and endocrine clinics of Zanjan city. Patients with fasting blood sugar between 90 and 125 mg/dL, Patients with HBA1C less than 6.5%, ALT greater than 1.5 to 5 times normal, Body mass index (BMI) ≥ 24 ; Exclusion criteria: Patients with other secondary causes of fatty liver (viral and alcoholic osteohepatitis, Wilson's disease, hemochromatosis, metabolic liver disease), Patients taking any type of medication that affects the liver (phenytoin, amiodarone, tamoxifen, birth control pills, levothyroxine, estrogen, corticosteroids, etc.)

Intervention groups

The experimental group consisted of 116 patients in two groups of 58 each with non-alcoholic fatty liver disease, prediabetes, and non-diabetes, who were treated with empagliflozin at doses of 10 mg and 25 mg for three months. This study selected 68 people who were divided

equally into two groups

Main outcome variables

AST, ALT, FIB-4, anthropometri

General information

Reason for update

Update results and corrections

Acronym

IRCT registration information

IRCT registration number: **IRCT20250314065071N1**

Registration date: **2025-03-17, 1403/12/27**

Registration timing: **prospective**

Last update: **2026-02-06, 1404/11/17**

Update count: **1**

Registration date

2025-03-17, 1403/12/27

Registrant information

Name

Mehran Nezamdiba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3343 6086

Email address

mehrandiba@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

2025-04-21, 1404/02/01
Actual recruitment end date
2025-08-23, 1404/06/01
Trial completion date
2025-09-23, 1404/07/01

Scientific title
Comparing the effects of doses empagliflozin 10 mg and 25 mg on anthropometric index and liver enzymes in patients with non alcoholic fatty liver (NAFLD)

Public title
Comparing the effects of doses empagliflozin 10 mg and 25 mg on anthropometric index and liver enzymes in patients with non alcoholic fatty liver (NAFLD)

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
patients with non alcoholic fatty liver (NAFLD)referred to Gastroenterology and endocrine clinics of Zanjan city Patients with fasting blood sugar between 90 and 125 mg/dL Patients with HBA1C less than 6.5% ALT greater than 1.5 to 5 times normal Body mass index (BMI) ≥ 24
Exclusion criteria:
Patients with other secondary causes of fatty liver (viral and alcoholic osteohepatitis, Wilson's disease, hemochromatosis, metabolic liver disease) Patients taking any type of medication that affects the liver (phenytoin, amiodarone, tamoxifen, birth control pills, levothyroxine, estrogen, corticosteroids, etc.)

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **116**
Actual sample size reached: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 68 people were selected and divided equally into two groups. (35 people in the 10 mg group and 33 people in the 25 mg group at the end of the study). The allocation of samples to two random block groups was done using sealed envelope sensitivity. For randomization, the block randomization method was used. To generate the random sequence, the website <https://www.sealedenvelope.com> was used online. Blocks of 6 people were designed and a total of 12 blocks of 6 were created, which ultimately randomly assigned 35 patients to the 10 mg group and 33 patients to the 25 mg group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel
Other design features
Comparing the effects of doses empagliflozin 10 mg and 25 mg on anthropometric index and liver enzymes in patients with non alcoholic fatty liver (NAFLD)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of medical Sciences

Street address

Zanjan, Azadi Boulevard, Zanjan University of Medical Sciences, Research Vice-Chancellor

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2025-03-04, 1403/12/14

Ethics committee reference number

IR.ZUMS.REC.1403.353

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

Aspart Aminotransferase (AST)

Timepoint

At the beginning of the study and after 12 weeks

Method of measurement

Aspart Aminotransferase specific laboratory kit

2

Description

Alanine Aminotransferase

Timepoint

At the beginning of the study and after 12 weeks

Method of measurement

Alanine Aminotransferase specific laboratory kit

3

Description

Average changes in FIB-4 criteria

Timepoint

At the beginning of the study and after 12 weeks

Method of measurement

Laboratory kit for Aspart Aminotransferase and Platelet, then using FIB-4 formula

4

Description

Anthropometric index includes weight, height, BMI, waist circumference, hip circumference, and waist-to-hip ratio.

Timepoint

At the beginning of the study and after 12 weeks

Method of measurement

The method of measuring the weight variable of individuals will be measured with a seca scale with an accuracy of 0.1 kg, without shoes and with minimal clothing. The height, waist and hip circumference of individuals will also be measured using a non-elastic meter with an accuracy of 0.5 cm. The body mass index will also be calculated for each individual with the formula $BMI = \frac{\text{weight (Kg)}}{\text{height (m)}^2}$. Also, the formula $WHR = \frac{\text{waist circumference}}{\text{hip circumference}}$ will be used to calculate the waist-to-hip ratio.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groupA: Recipients will receive 10 mg of empagliflozin once daily for 3 months, and a weight-stabilizing diet that provides 26-27 kcal per kilogram of energy, with 50-55% of daily energy coming from carbohydrates, 15% from protein, and 30-35% from fat, will be adjusted for patients. Anthropometric index as well as paraclinical data including AST, ALT, CBC will be recorded at the beginning and end of the study. Also, FIB4 index will be calculated using the formula.

Manufacturer: Abidi Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Intervention groupB: Recipients will receive 25 mg of empagliflozin once daily for 3 months, and a weight-stabilizing diet that provides 26-27 kcal per kilogram of energy, with 50-55% of daily energy coming from carbohydrates, 15% from protein, and 30-35% from fat, will be adjusted for patients. Anthropometric index as well as paraclinical data including AST, ALT, CBC will be recorded at the beginning and end of the study. Also, FIB4 index will be calculated using the formula.

Manufacturer: Abidi Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan, Vali-e-Asr Hospital

Full name of responsible person

Dr. Mehran Nezam Diba

Street address

Zanjan, Valiasr Square, Valiasr Hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Phone

+98 24 3373 9028

Email

Mehrandiba@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

Street address

Zanjan, Sheikh Fadlallah Nouri Highway, Valiasr Square, Valiasr Hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Phone

+98 24 3373 9028

Email

hamidim@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Sahar Shafagh

Position

Resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Zanjan, Sheikh Fadlallah Nouri Highway, Valiasr Square, Valiasr Hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Phone

+98 24 3373 9028

Email

Saharshafagh323@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Mehran Nezam Diba

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Zanjan, Sheikh Fadlallah Nouri Highway, Valiasr Square, Valiasr Hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Phone

+98 24 3373 9028

Email

Mehrandiba@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Sahar Shafagh

Position

Resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Zanjan, Sheikh Fadlallah Nouri Highway, Valiasr Square, Valiasr Hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Phone

+98 24 3373 9028

Email

Saharshafagh323@gmail.com

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

Age, gender, and demographic information of patients, as well as test results and questionnaires containing patients' symptoms at the beginning, during, and end of the treatment period, with the removal of patients' personal details, as well as some of the data, such as information related to the main outcome, can be published.

When the data will become available and for how long

When publishing, documents and files will be available online after the completion of the project with the permission of the Ethics Committee of Zanjan University of Medical Sciences

To whom data/document is available

Researchers working in universities and scientific institutions

Under which criteria data/document could be used

By adhering to the ethical principles of confidentiality,

information, documentation, and all investigations conducted can be published.

From where data/document is obtainable

Mehrandiba@zums.ac.ir

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

Send an email and make a request

Comments