Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of empagliflozin on thyroid function in patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Study aim

Determination the effect of Empagliflozin on thyroid function in patients with non-alcoholic fatty liver disease (NAFLD) referred to Shahid Mofateh Clinic in Yasuj city

Design

The clinical trial will have a control group, with parallel groups, double-blind, blocked randomization, phase 3 on 40 patients, the sample size in each group will be 20 people. The software used is G power version 3.1.9.4.

Settings and conduct

After identifying patients eligible for inclusion in the study from among those referred to the Shahid Mofatteh Clinic , the patients were divided into two groups in a block randomization manner providing.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study were non-alcoholic fatty liver disease (NAFLD) on ultrasound in individuals over 18 years of age, as well as ALT greater than 33 in men and greater than 25 in non-diabetic women. After identifying the patients, they were divided into two groups of 20 . Exclusion criteria:Alcohol consumption more than 20 grams per day/History of hepatitis B or C virus infection/Autoimmune hepatitis/Other liver diseases/Taking any hepatotoxic or thyroid medication/Diabetes/Pregnancy/breastfeeding/History of cancer or treatment for thyroid cancer within the past 2 years/BMI more than 40

Intervention groups

Initially, tests (ALT, AST, Fatty liver grade 1, grade 2, grade 3, T4, TSH) are taken from all individuals in both groups. Then, for the experimental group, the drug empagliflozin (10 mg/day)(4) is prescribed once a day orally, along with a diet and exercise program, and for the control group, only a diet and exercise program is applied.The exercise program includes 30 minutes of daily walking, and the diet plan includes a 10% reduction in daily calorie intake from carbohydrate intake

Main outcome variables

ALT; AST; ALKP; TSH; T4; T3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250713066469N1**
Registration date: **2025-07-30, 1404/05/08**
Registration timing: **prospective**

Last update: **2025-07-30, 1404/05/08**
Update count: **0**

Registration date

2025-07-30, 1404/05/08

Registrant information

Name

Neda Saeedinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 9236

Email address

neda.sdi77@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empagliflozin on thyroid function in patients with non-alcoholic fatty liver disease (NAFLD)

Public title

Investigating the effect of empagliflozin on thyroid function in patients with non-alcoholic fatty liver disease (NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 30 to 70 years Non-alcoholic fatty liver disease (confirmed by ultrasound)

Exclusion criteria:

Alcohol consumption of more than 20 grams per day History of hepatitis B or C virus infection, autoimmune hepatitis, other liver diseases Taking any hepatotoxic or thyroid medications pregnancy / breastfeeding History of cancer or treatment for thyroid cancer within the past 2 years BMI more than 40

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking will be used to assign individuals to the study groups. The advantages of blocked randomization are that it ensures a balance in the number of patients in each group. The groups are defined as codes A and B. Before assigning individuals to one of the groups, a list of these letters (A, B) is formed, in other words, blocks. Each of the referring and eligible individuals is assigned to one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding was performed for patients and the researcher and they were unaware of the drug group they received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj univercity of medical scienes

Street address

Yasuj university of medical seinces; Motahari Blvd; Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Approval date

2025-04-23, 1404/02/03

Ethics committee reference number

IR.YUMS.REC.1404.007

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

TSH

Timepoint

o-3-6 months

Method of measurement

Fasting venous whole blood samples will be obtained to measure the biochemical parameters of thyroid-stimulating hormone, thyroxine and triiodothyronine. All values will be measured by standard methods.

2

Description

T4

Timepoint

o-3-6 months

Method of measurement

Fasting venous whole blood samples will be obtained to measure the biochemical parameters of thyroid-stimulating hormone; thyroxine and triiodothyronine. All values will be measured by standard methods.

3

Description

T3

Timepoint

o-3-6 months

Method of measurement

Fasting venous whole blood samples will be obtained to

measure the biochemical parameters of thyroid-stimulating hormone; thyroxine and triiodothyronine. All values will be measured by standard methods.

Secondary outcomes

1

Description
Alanine aminotransferase
Timepoint
0-3-6 months
Method of measurement
Fasting venous whole blood samples will be obtained to measure the biochemical parameters alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALKP), high density lipoprotein (HDL).

2

Description
Aspartate aminotransferase
Timepoint
0-3-6 months
Method of measurement
Fasting venous whole blood samples will be obtained to measure the biochemical parameters alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALKP), high density lipoprotein (HDL).

3

Description
Alkaline phosphatase
Timepoint
0-3-6 months
Method of measurement
Fasting venous whole blood samples will be obtained to measure the biochemical parameters alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALKP), high density lipoprotein (HDL).

4

Description
fatty liver grade
Timepoint
0-3-6 months
Method of measurement
Fasting venous whole blood samples will be obtained to measure the biochemical parameters alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALKP), high density lipoprotein (HDL).

Intervention groups

1

Description
They received the drug empagliflozin.
Category
Treatment - Drugs

2

Description
Control group: Diet and exercise
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofatteh 2 Clinic, Yasuj
Full name of responsible person
Mohamad Marashi
Street address
Golestan 15 street
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Yasuj
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Kohgilouyeh-va-Boyrahmad
Postal code
7591765432
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+98 74 9101 3813
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cngfdgnfn@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Sirus Salehnasab
Street address
Yasuj University of Medical Sciences Headquarters; Motahari Blvd
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7591741417
Phone
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Email
research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Neda Saeedinasab

Position
Intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Position
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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
I haven't decided yet.

When the data will become available and for how long
one yeari

To whom data/document is available
I haven't decided yet.

Under which criteria data/document could be used

...

From where data/document is obtainable

Yasuj university of medical sciencesهنوز تصمیم

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

I haven't decided yet.

Comments