Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Empagliflozin on Liver Enzymes level in type two Diabetic Patients with Non-Alcoholic Steatohepatitis

Protocol summary

Study aim

The primary outcome is determining the effect of empagliflozin on liver enzymes and the secondary outcomes include determining the effect of empagliflozin on lipid profile and indicators of metabolic syndrome in patients with type 2 diabetes and nonalcoholic steatohepatitis.

Design

Phase three double-blind, randomized clinical trial with a control group, with parallel groups, on 110 patients, randomization was done with website "sealedenvelope.com"

Settings and conduct

The study will recruit in Ayatollah Rouhani Hospital of Babol and Omid Babol Special Clinic. Sampling will be done among available eligible people. Each patient will be assigned a special code based on a random list and the patient will be placed in the intervention or control group based on it. The patient, the physician in charge of the plan, the person in charge of patient recruitment and registration of patient information, the person in charge of evaluating the study parameters, and the data analyst are all blind to the patient group and only know the code assigned to each person. One of the researchers in the group, who has no role in the patient recruitment, treatment and evaluation of the study parameters, has access to a random list containing the patient's specific code and the corresponding treatment.

Participants/Inclusion and exclusion criteria

Study population: Type 2 diabetic patients with non-alcoholic steatohepatitis inclusion criteria: age between 18 to 85 years old, body mass index less than 35 kg per square meters

Intervention groups

Intervention group: Standard treatment for type 2 diabetes with one empagliflozin 10 mg tablet daily
Control group: Standard treatment for type 2 diabetes with one placebo tablet daily

Main outcome variables

Aspartate transaminase; Alanine transaminase; Alkaline phosphatase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210609051526N2**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Neda Meftah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3233 8301

Email address

n.meftah@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Empagliflozin on Liver Enzymes level in type two Diabetic Patients with Non-Alcoholic Steatohepatitis

Public title
Effect of Empagliflozin in diabetic patients with non-alcoholic steatohepatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Body mass index less than 35 Kg/mm No history of chronic alcohol usage No history of viral hepatities No history of autoimmune hepatitis No history of drug-induced hepatitis No history of chronic usage of hepatic-steatosis-induced drugs(e.g.: Amiodarone, Valproate, Tamoxifen, Methotrexate, Glucocorticoids) No history of chronic usage of Thiazolidines and GLP-1 agonists Absence of evidence suggestive for cirrhosis based on physical examination, laboratory evaluation, and imaging studies Absence of evidence suggestive for Hepatocellular carcinoma based on physical examination, laboratory evaluation, and imaging studies Non pregnant women No previous history of HELLP syndrome in women No history of chronic kidney disease No history of chronic usage of Omega-3 containing supplements No contraindication for Empagliflozin usage (e.g.: history of recurrent genitourinary tract infection, gangrene, history of allergic reaction to the drug, serum Trigliceride level more than 500 mg/dl)

Exclusion criteria:

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
We will assign each person to one of the two study groups in a one-to-one ratio using the random block method. Using the site www.sealedenvelope.com, with seed number 186476011923636 and block size 4 and the length of the list 110 and the code specific to each person, we made a random list, which we gave to a member of the research team who has no role in patient recruitment and data analysis. The person in charge of patients recruitment will call the person who has a random list and receive a code specific to the patient and assign it to the patient. The treatment protocol will be performed based on the code assigned to The patient. The person in charge of the patient's follow-up and data analysis will not be aware of the treatment protocol used for that person.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participant will be kept blind from receiving a drug or placebo by using a placebo with the same shape, color, and size as the drug. The clinician only knows the code assigned to the patient and does not know the patient's treatment. Only one researcher from the research team, who has no role in patient recruitment and data analysis, has access to the randomization list containing each individual's specific code and treatment protocol and does not reveal it to anyone except in life-threatening cases or based on the decision of the university ethics committee. The outcome assessor only has access to the code assigned to the patient and does not know the treatment protocol of that code. The data analyzer does not know each patient's treatment protocol, and we will provide the coded data to him.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47745-47176

Approval date
2021-08-31, 1400/06/09

Ethics committee reference number
IR.MUBABOL.REC.1400.186

Health conditions studied

1

Description of health condition studied
non-alcoholic steatohepatitis

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

Aspartate transaminase

Timepoint

Before the start of the study, 12 and 24 weeks after the start of treatment

Method of measurement

Serum level measurement

2

Description

Alanine transaminase

Timepoint

Before the start of the study, 12 and 24 weeks after the start of treatment

Method of measurement

Serum level measurement

3

Description

Alkaline phosphatase

Timepoint

Before the start of the study, 12 and 24 weeks after the start of treatment

Method of measurement

Serum level measurement

4

Description

body weight

Timepoint

Before the start of the study, 12 and 24 weeks after the start of treatment

Method of measurement

Using scales and in kilograms

5

Description

weight cirmucfrences

Timepoint

Before the start of the study, 12 and 24 weeks after the start of treatment

Method of measurement

Using meters and in centimeters

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Standard treatment for type 2 diabetes with one 10 mg Empagliflozin tablet daily

Category

Treatment - Drugs

2

Description

Control group: Standard treatment for type 2 diabetes with one placebo tablet daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital of Babol

Full name of responsible person

Neda Meftah

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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2

Recruitment center

Name of recruitment center

Omid Therapy Clinic

Full name of responsible person

Neda Meftah

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Reza Ghadimi
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Email
rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Neda Meftah
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
We can share the collected data with unidentified individuals.

When the data will become available and for how long
Six months after, we can share the publication of the article extracted from the data plan.

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
The researcher announces his proposal and the required data to the project manager to provide the data to him if possible.

From where data/document is obtainable
The person responsible for the scientific responsibility of the trial

What processes are involved for a request to access data/document
The researcher should send the request to the email of the person responsible for the scientific responsibility of the project.

Comments