Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Effects of Liraglutide on Metabolic Parameters, Liver Function, and Non-Invasive Liver Fibrosis Indices in Patients with Type 2 Diabetes and Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD): A Randomized Controlled Trial

Protocol summary

Study aim

To evaluate and compare the efficacy and tolerability of Liraglutide versus standard care on metabolic parameters (FBS, HbA1c, BMI), liver function tests (ALT, AST), and non-invasive liver fibrosis indices (FIB-4, LSM, CAP) in patients with Type 2 Diabetes Mellitus and Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD).

Design

Randomized, Open-label, Controlled, Parallel-group Clinical Trial.

Settings and conduct

The study will be conducted at Baqiyatallah hospital. After screening and informed consent, patients will be randomly assigned to two groups: Intervention (Liraglutide added to standard care) and Control. The intervention duration is 12 weeks. Data collection includes laboratory tests, FibroScan (CAP/LSM), and calculated indices (FIB-4).

Participants/Inclusion and exclusion criteria

Inclusion: Age 35-65 years. BMI between 27-40 kg/m². Confirmed diagnosis of Type 2 Diabetes. Stable antidiabetic regimen for at least 3 months. Confirmed hepatic steatosis (CAP ≥ 245 dB/m) via FibroScan. Exclusion: Significant alcohol consumption (>30g/day for men, >20g/day for women). History of acute pancreatitis. Pregnancy or lactation. Concomitant use of other GLP-1 receptor agonists. Need for changes in antidiabetic medication dosage in the past 12 weeks.

Intervention groups

Intervention Group: Daily subcutaneous Liraglutide. Dose titration: 0.6 mg (Week 1), 1.2 mg (Week 2), and 1.8 mg (Week 3 onwards). Patients continue their previous antidiabetic medications at fixed doses (with prophylactic dose reduction of sulfonylureas/insulin if necessary). Control Group: Standard care (previous medications at fixed doses + lifestyle education).

Main outcome variables

Change in liver steatosis level (CAP index in FibroScan) from baseline to Week 12. Change in anthropometric indices (Weight and BMI) from baseline to Week 12.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260602069614N1**
Registration date: **2026-06-12, 1405/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-12, 1405/03/22**
Update count: **0**

Registration date

2026-06-12, 1405/03/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-03, 1405/03/13

Expected recruitment end date
2026-12-07, 1405/09/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effects of Liraglutide on Metabolic Parameters, Liver Function, and Non-Invasive Liver Fibrosis Indices in Patients with Type 2 Diabetes and Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD): A Randomized Controlled Trial

Public title
Effects of Liraglutide on Liver Fat and Metabolic Indices in Type 2 Diabetes Patients with MASLD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 35-65 years BMI between 27-40 kg/m² Confirmed diagnosis of Type 2 Diabetes Stable antidiabetic regimen for at least 3 months Confirmed hepatic steatosis (CAP ≥ 245 dB/m) via FibroScan
Exclusion criteria:
Significant alcohol consumption (>30g/day for men, >20g/day for women) History of acute pancreatitis Pregnancy or lactation Concomitant use of other GLP-1 receptor agonists Need for changes in antidiabetic medication dosage in the past 12 weeks
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to intervention and control groups using permutation blocks of 4 (Block Size 4) and a ratio of 1:1. Random sequences were generated by a statistician using the online Sealed Envelope tool for two fibrosis classes (less than 8 and greater than or equal to 8 kPa). The independent investigator assigned and notified the group after receiving the patient code.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is open-label for both the patient and the physician, as the method of administering liraglutide (daily injection with dose titration) is different from the control group. However, the FibroScan machine operator and the biostatistician are completely blinded to the patients' treatment group to avoid bias in the assessment of the primary and secondary outcomes.
Placebo
Not used
Assignment
Parallel
Other design features
کارآزمایی بالینی موازی. مدت مداخله ۱۲ هفته. پیگیری‌ها شامل معاینات و آزمایش‌های دوره‌ای در هفته‌های ۴، ۸ و ۱۲ است. معیارهای ارزیابی بر اساس فیبرواسکن، آزمایش خون و شاخص‌های محاسباتی است.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Mulla Sadra, Vanak Square, Tehran, Iran
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Tehran
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1435915381
Approval date
2026-05-18, 1405/02/28
Ethics committee reference number
IR.BMSU.BAQ.REC.1405.005

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

2

Description of health condition studied
Metabolic Syndrome-Associated Fatty Liver Disease (MASLD)
ICD-10 code
K75.81
ICD-10 code description
Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
Changes in the hepatic steatosis index (CAP)
Timepoint
1. Baseline: Before initiation of Liraglutide.2. End of Intervention: Week 12 (12 weeks) after starting treatment.
Method of measurement
Non-invasive measurement using FibroScan® device.The operator must be blinded to the patient's treatment group. Two consecutive measurements are performed for each patient, and the mean is recorded as the final result (if the difference is >10%, a third measurement is taken).

2

Description
Changes in body mass index (BMI)
Timepoint
1. Baseline: Before initiation of Liraglutide.2. End of Intervention: Week 12 (12 weeks) after starting treatment.
Method of measurement
Direct measurement of weight and height.Weight is measured using a calibrated digital scale (light clothing, barefoot) and height using a stadiometer (barefoot). BMI is calculated as kg/m².

Secondary outcomes

1

Description
Liver Stiffness Index (LSM)
Timepoint
1. Baseline: Before initiation of Liraglutide.2. End of Intervention: Week 12 (12 weeks) after starting treatment.
Method of measurement
Measurement using FibroScan® device.The mean of 10 successful measurements (with success rate ≥60% and IQR <30% of the median) is recorded.

2

Description
Liver enzymes (ALT and AST)
Timepoint
1. Baseline: Before initiation of Liraglutide.2. End of Intervention: Week 12 (12 weeks) after starting treatment.
Method of measurement
Biochemical blood test.A venous blood sample is taken after 8-10 hours of fasting and measured in the hospital's reference laboratory (ISO 15189 standard) using standard enzymatic methods. The unit is U/L.

3

Description
Glycosylated hemoglobin (HbA1c)
Timepoint
1. Baseline: Before initiation of Liraglutide.2. End of Intervention: Week 12 (12 weeks) after starting treatment.
Method of measurement
Biochemical blood test.Measurement performed via High-Performance Liquid Chromatography (HPLC) or validated immunological methods in the reference laboratory. The unit is percentage (%).

4

Description
Side effects and tolerability
Timepoint
Continuous Follow-up: At weekly/monthly visits during the 12-week period and at the end of the 12-week course.
Method of measurement
Clinical interview and standard checklist.The researcher records adverse events by interviewing the patient and observing clinical signs, categorizing them by severity (mild, moderate, severe) and causal relationship to the drug.

Intervention groups

1

Description
Intervention group: Daily subcutaneous Liraglutide. Dose titration: 0.6 mg (Week 1), 1.2 mg (Week 2), and 1.8 mg (Week 3 onwards). Patients continue their previous antidiabetic medications at fixed doses (with prophylactic dose reduction of sulfonylureas/insulin if necessary).
Category
Treatment - Drugs

2

Description
Control group: Standard care (previous medications at fixed doses + lifestyle education).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
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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 un-identification of individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic centers as well as to industry professionals.

Under which criteria data/document could be used

Statistical analyzes on data are allowed for scientific and research use after obtaining permission from the project manager.

From where data/document is obtainable

For data and documentation, refer to the Research Center for Gastroenterology and Liver Diseases and Dr. Mohammad Ali Abyazi Herris.

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

After receiving a written request from researchers... by the Baqiyatallah Research Center for Gastroenterology and Liver Disease and reviewing the application in the Research Council of the Research Center, the documents or data files will be delivered to the applicant after about 10 days.

Comments