Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Impact of Optimal Glycemic Control on the FIB-4 Index in Patients with Type 2 Diabetes and Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD)

Protocol summary

Study aim
"Investigating the effects of glycemic control on the FIB-4 index in patients with type 2 diabetes and metabolic dysfunction-associated steatotic liver disease (MASLD)

Design
Clinical trial without a control group, single-arm, unblinded, non-randomized, Phase 3, involving 83 patients.

Settings and conduct
Location: Clinics and via public recruitment. Method: Convenience sampling method Questionnaire and consent form completion. Measurement of weight, height, waist and hip circumference.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals aged 18 to 65 years with type 2 diabetes and metabolic dysfunction-associated steatotic liver disease (MASLD) Exclusion criteria: Pregnancy and breastfeeding, history of psychiatric illness and use of antipsychotics, history of viral hepatitis, autoimmune hepatitis, liver or kidney transplant, history of rheumatologic diseases, alcohol consumption history, glucocorticoid use history, other types of diabetes (such as type 1 diabetes, MODY, etc.), recent surgery within the last three months, chronic neurological diseases, chronic hepatitis C infection, alcoholic liver disease, severe and incurable diseases, Cushing's syndrome, rheumatoid arthritis, cancer, use of osteoigenic drugs.

Intervention groups
glycemic control based on HbA1C lower than 7%

Main outcome variables
FIB-4 index; Glycemic control; Anthropometric measures

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250506065618N1**
Registration date: **2025-07-17, 1404/04/26**
Registration timing: **prospective**

Last update: **2025-07-17, 1404/04/26**
Update count: **0**

Registration date
2025-07-17, 1404/04/26

Registrant information

Name
Maedeh Zolfi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3365 8429

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maedehzolfi34@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-22, 1404/04/31

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Impact of Optimal Glycemic Control on the FIB-4 Index in Patients with Type 2 Diabetes and Metabolic

Dysfunction Associated Steatotic Liver Disease (MASLD)

Public title
The Impact of Optimal Glycemic Control on the FIB-4 Index in Patients with Type 2 Diabetes and Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals aged 18 to 65 years with type 2 diabetes and metabolic dysfunction-associated steatotic liver disease (MASLD) Willingness to cooperate

Exclusion criteria:
Pregnancy history of psychiatric illness and use of antipsychotics history of viral hepatitis, autoimmune hepatitis liver or kidney transplant history of rheumatologic diseases alcohol consumption history glucocorticoid use history other types of diabetes (such as type 1 diabetes, MODY, etc.) recent surgery within the last three months chronic neurological diseases chronic hepatitis C infection alcoholic liver disease severe and incurable diseases Cushing's syndrome rheumatoid arthritis use of osteoigenic drugs patients with other types of diabetes cancer breastfeeding

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **83**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2025-03-14, 1403/12/24

Ethics committee reference number
IR.TBZMED.REC.1403.1103

Health conditions studied

1

Description of health condition studied
(Type 2 Diabetes) (MASLD - Metabolic Dysfunction-Associated Steatotic Liver Disease) (Liver Fibrosis) (Glycemic Control) (Anthropometric Indices)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Changes in the FIB-4 index: The extent of change in this index after the intervention (glycemic and anthropometric control) will be the primary evaluation criterion. The aim is to determine whether controlling blood sugar and anthropometric indices can lead to an improvement (reduction) in the FIB-4 index.

Timepoint
before the intervention starts and 6 months after it begins, in order to assess the impact of glycemic and anthropometric control on the FIB-4 index and other variables."

Method of measurement
IB-4 Index:Calculation Method: Calculated using the following formula:Age (years) x AST (IU/L) / (PLT (10^9/L) x √ALT (IU/L))AST: Aspartate AminotransferaseALT: Alanine AminotransferasePLT: Platelet countUnit of Measurement: Unitless (numerical value)Glycemic Indices:Fasting Blood Glucose (FBG):Measurement Device: Standard laboratory glucometerUnit of Measurement: Milligrams per deciliter (mg/dL)Glycated Hemoglobin (HbA1c):Measurement Method: Immunoassay or High-Performance Liquid Chromatography (HPLC)Unit of Measurement: Percentage (%)Anthropometric Indices:Weight:Scale: Standard digital scaleUnit of Measurement: Kilograms (kg)Height:Stadiometer: Fixed stadiometerUnit of Measurement: Centimeters (cm)Waist Circumference:Measurement Method: Using a measuring tape at the narrowest part of the waist, between the last rib and the pelvic bone.Unit of Measurement: Centimeters (cm)Hip Circumference:Measurement Method: Using a measuring tape at the widest part of the hips.Unit of Measurement: Centimeters (cm)Body Mass Index (BMI):Calculation Method: Weight (kg) divided by height (meters) squaredUnit of Measurement: Kilograms per square meter (kg/m²)Dietary Intake:Questionnaire:

24-hour dietary recall questionnaireEvaluation Method: Analysis of questionnaire data by a nutritionist or using nutritional analysis software.

Secondary outcomes

1

Description
Dietary Habits
Timepoint
t the beginning of the study, before any intervention is implemented and At the end of the intervention period
Method of measurement
3-Day Food Diary: Participants will be instructed to record all food and beverages consumed over three consecutive days. Detailed instructions on how to record the food intake will be provided. Registered dietitians will provide training to participants on how to properly fill out the diary.

Intervention groups

1

Description
The participants in this study are adult aged 18-65 years with type 2 diabetes and metabolic dysfunction-associated steatotic liver disease (MASLD), who will be followed for 6 months. These individuals will receive pharmaceutical and dietary interventions to control their glycemic and anthropometric status. In other words, the intervention group is a group of individuals who will undergo a series of interventions (pharmaceutical and dietary) to improve their glycemic and anthropometric status, and the effect of these interventions on the FIB-4 index will be investigated. Hemoglobin A1C less than 7% will be considered as good glycemic control.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikh Al-Raees Clinic inTabriz
Full name of responsible person
Dr Mahsa Malekian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
University Research Vice-Chancellor’s Office
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mahsa Malekian
Position
Associate professor
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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
Undecided - It is not yet known if there will be 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
Deidentified Individual Participant Data Set (IPD): If feasible, the complete dataset related to the participants, after removing identifying information (such as names, contact information, etc.), will be shared. If sharing the entire dataset isn’t possible, a portion of the data, such as information related to the primary outcomes (FIB-4 index, blood glucose levels, anthropometric indices) and demographic variables, will be shared. Study Protocol: The complete study protocol, including objectives, hypotheses, methods, inclusion and exclusion criteria, and data collection methods, will be shared. Statistical Analysis Plan: The complete statistical analysis plan, including the statistical methods used, statistical assumptions, and data analysis plans, will be shared. Informed Consent Form: The informed consent form used in the study will be shared (ensuring the removal of any identifying information). Clinical Study Report: The complete clinical study report, including findings, results, discussion, and conclusions, will be shared. Analytic Codes: The analytic codes used for data analysis (such as SPSS or R code) will be shared. Data Dictionary: The data dictionary, including descriptions of variables, units of measurement, and possible values for each variable, will be shared.
When the data will become available and for how long
Initial Data Release (Study Protocol, Statistical Analysis Plan, Informed Consent Form): Timeline: These documents will be prepared for release within 3 months following the completion of the primary data collection phase of the study. Main Data Release (Deidentified IPD, Clinical Study Report, Analytic Codes, Data Dictionary): Timeline: These files will be prepared for release within 6 months following the completion of the initial data analysis and the preparation of the first draft of the study manuscript. Additional Notes: Contingencies: These timelines are contingent upon the successful completion of data collection, data analysis, and the preparation of the initial manuscript. Unexpected delays in any of these stages may affect the release dates.
To whom data/document is available

Academic and Scientific Researchers: This group certainly includes researchers from universities, research institutions, and other scientific centers who need the data to conduct further research and confirm or refute the findings of the original study. Researchers Employed in Industry: Individuals working in pharmaceutical, biotechnology, or other health-related industries can also request data. This helps in the development of new drugs and therapies and improves healthcare. Other Healthcare Professionals: Physicians, nurses, and other healthcare professionals seeking to improve the care of their patients can also benefit from the study's data and findings. General Public: In some cases, access to data is also provided to the general public, especially if the goal is to increase awareness and public participation in scientific research. Of course, in this case, it must be ensured that the data is published in a de-identified manner to protect the privacy of the participants.

Under which criteria data/document could be used

Purpose of Use: The data and documentation must be used solely for research, educational, or healthcare improvement purposes. Commercial use of the data (such as selling the data to third parties) is not permitted. Type of Analysis: Statistical and epidemiological analyses to answer research questions related to the study are permitted. Attempts to identify the identity of participants or use the data in a way that violates their privacy are prohibited. Publication of Results: The results of data analysis must be published in the form of scientific articles, reports, or presentations. All publications must refer to the original study and the source of the data. No part of the data or results should be published in a way that violates the privacy of the participants. Data Storage and Protection: Data and documentation must be stored securely and in a protected location. Access to the data must be limited to those who have permission to use it. Data should not be transferred to any third party without written permission from the original research team. Mechanisms Governing the Use of Data: Data Transfer Agreement (DTA): Before accessing the data, the applicant must sign a Data Transfer Agreement specifying the terms of use of the data. This agreement must include a commitment to ethical principles, respect for the privacy of participants, and non-commercial use of the data. Ethical Review: In some cases, the applicant may be required to provide ethical approval from their institution's ethics committee for the use of the data. Monitoring: The original research team may monitor the use of the data to ensure that the terms of use are respected. Requirements for Submitting a Request for Access to Data and Documentation: Applicant Information: First and last name Organizational affiliation (university, research institute, company, etc.) Contact information (email, phone) Job or educational position Summary of educational and research background Purpose of Using the Data: A detailed explanation of why the applicant needs the data and what research questions they want to answer. Description of the data analysis plan and the statistical methods to be used. Commitments: Commitment to respecting ethical principles and protecting the privacy of participants. Commitment to not using the data for commercial purposes. Commitment to refer to the original study and the source of the data in all publications. Commitment not to transfer the data to third parties without written permission from the original research team. Commitment to store and protect the data securely.

From where data/document is obtainable

Contacting the Original Research Team: This method is usually the best and most direct way to obtain accurate and up-to-date information on how to access the data and documentation. Unfortunately, the proposal does not mention the name or contact information of the individual or individuals responsible for responding to requests. It is recommended to search for the contact information of the authors of the proposal (especially Dr. Mahsa Malekian and Dr. Amin Sadrazar) by searching for articles published by them or through the website of the university or institution where they work.

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

Request for Access: The requester must submit a formal written request to the original research team. The request should include the following: The specific purpose for which the data and documentation are requested (e.g., for meta-analysis, replication of the study). A list of specific required documents or data files. A description of how the requester will maintain data confidentiality and ethical principles. The requester's contact information (name, address, email, phone number).

Comments