Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Daily versus Alternate-Day Combination Therapy with Atorvastatin and Fenofibrate in mixed hyperlipidemia

Protocol summary

Study aim

Evaluation of the efficacy of combination therapy in combined hyperlipidemia with fibrate and statin drugs in diabetic patients

Design

Study Design (Summary): This prospective, single-center, randomized, open-label clinical trial was conducted at Khatam Hospital in Shahrood, Iran, from September 2024 to December 2025. It involved patients with concurrent dyslipidemia and type 2 diabetes mellitus (T2DM). Eligible participants (males and females, aged 18–80 years) were randomized into two groups: daily treatment (atorvastatin 10 or 20 mg and fenofibrate 100 mg) and alternate-day treatment for 12 weeks. The study adhered to the Declaration of Helsinki and ICH-GCP guidelines.

Settings and conduct

This prospective, single-center, randomized, open-label clinical trial was conducted at Khatam Hospital in Shahrood, Iran, from September 2024 to December 2025.

Participants/Inclusion and exclusion criteria

Confirmed diagnosis of type 2 diabetes mellitus (T2DM) per American Diabetes Association criteria: HbA1c ≥6.5%, fasting plasma glucose ≥126 mg/dL, or 2-hour plasma glucose ≥200 mg/dL during an oral glucose tolerance test. LDL-C >100 mg/dL and TG >200 mg/dL, indicating mixed dyslipidemia. Body mass index (BMI) 18.5–40 kg/m². Stable antidiabetic therapy for at least 3 months prior to enrollment. Willingness to provide written informed consent.

Intervention groups

1. Alternate-day therapy 2.daily therapy

Main outcome variables

1.alanine aminotransferase 2.aspartate aminotransferase 3.total cholesterol 4.low-density lipoprotein cholesterol (LDL) 5.high-density lipoprotein cholesterol (HDL) 6.triglyceride

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250718066536N1**
Registration date: **2025-07-25, 1404/05/03**
Registration timing: **prospective**

Last update: **2025-07-25, 1404/05/03**
Update count: **0**

Registration date

2025-07-25, 1404/05/03

Registrant information

Name

Soheil Shahramirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3740 8566

Email address

soheil.rad2019@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-19, 1404/05/28

Expected recruitment end date

2026-08-19, 1405/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Daily versus Alternate-Day Combination Therapy with Atorvastatin and Fenofibrate in mixed hyperlipidemia

Public title
Comparison of daily and every-other-day combination therapy with statins and fibrates in patients with combined hyperlipidemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
· LDL-C exceeds 100 mg/dL and triglycerides surpass 200 mg/dL, indicating mixed dyslipidemia. The Body Mass Index (BMI) ranges from 18.5 to 40 kg/m². · Diabetes treatment that has been maintained for a minimum of three months prior to enrollment. Ability to provide written informed consent.
Exclusion criteria:
· Ongoing treatment for dyslipidemia four weeks prior to enrollment.· Triglyceride concentrations exceeding 500 mg/dL (5.6 mmol/L).· Active hepatic disease occurs when liver enzymes (SGOT, SGPT, or alkaline phosphatase) exceed three times the normal upper limit.· Renal impairment characterized by a serum creatinine concentration exceeding 1.6 mg/dL (141 µmol/L) or an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m².· Unmanaged Type 2 Diabetes Mellitus (HbA1c >7% and fasting blood glucose >126 mg/dL [7.0 mmol/L]).· Hypothyroidism occurs when thyroid-stimulating hormone levels exceed 5 IU/mL.· A history of myopathy or creatine phosphokinase (CPK) levels exceeding five times the normal upper limit.· A recent heart attack, coronary artery bypass grafting, percutaneous transluminal coronary angioplasty, or stroke occurring within the last six months.· Additional medications that may influence the metabolism of the study drug in the body (e.g., cytochrome P450 3A4 inhibitors).· Women undergoing hormone replacement therapy post-menopause.· Pregnant or breastfeeding women.· Patients unwilling to provide informed consent.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Write the name, code or number of each member on a piece of paper and then place it in a box or container and mix them well. Then take the paper according to the sample size and select the samples. Finally, from the list and according to the code given to each member or the number of each member, the samples are identified.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Shahrood Branch
Street address
Heasabi avenue
City
Shahrood
Province
Semnan
Postal code
7157759318
Approval date
2024-03-16, 1402/12/26
Ethics committee reference number
IR.IAU.SHAHROOD.REC.1402.107

Health conditions studied

1

Description of health condition studied
Dyslipidemia and Type 2 Diabetes Mellitus
ICD-10 code
E78 (Dysli
ICD-10 code description
E78: Disorders of lipoprotein metabolism and other lipidemias (for dyslipidemia)E11: Type 2 diabetes mellitus

Primary outcomes

1

Description
Primary Outcome Variable 1: Reduction in low-density lipoprotein cholesterol (LDL-C) levels (mg/dL)Description: The primary outcome is the change in LDL-C levels, measured as the difference between baseline and 12-week post-treatment values in patients with dyslipidemia and type 2 diabetes mellitus.Primary Outcome Variable 2: Reduction in triglyceride (TG) levels (mg/dL)Description: The primary outcome is the change in TG levels, measured as the difference between baseline and 12-week post-treatment values in patients with dyslipidemia and type 2 diabetes mellitus.

Timepoint
Time Points: Measurements of low-density lipoprotein cholesterol (LDL-C) and triglyceride (TG) levels were taken at baseline (before intervention) and after 12 weeks of treatment.
Method of measurement
Method for LDL-C: Measured using the Pars Azmoon Lipid Profile Kit with standardized enzymatic methods.Method for TG: Measured using the Pars Azmoon Lipid Profile Kit with standardized enzymatic methods.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Daily Treatment GroupPatients received atorvastatin (10 or 20 mg, oral, once daily) and fenofibrate (100 mg, oral, once daily) for 12 weeks. Atorvastatin and fenofibrate were manufactured by [Insert Manufacturer Name], and the dosage was determined based on clinical guidelines and patient-specific factors.Intervention Group 2: Alternate-Day Treatment GroupPatients received atorvastatin (10 or 20 mg, oral, every other day) and fenofibrate (100 mg, oral, every other day) for 12 weeks. Atorvastatin and fenofibrate were manufactured by [Insert Manufacturer Name], with the alternate-day dosing schedule designed to assess efficacy and tolerability compared to daily dosing.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam hospital of shahrood
Full name of responsible person
Dr Nasrin Razavianzadeh
Street address
Hesabi avenue
City
Shahrood
Province
Semnan
Postal code
7157759318
Phone
+98 71 3740 8566
Email
soheil.rad2019@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nasrin Razavianzadeh
Street address
Hesabi avenue
City
Shahrood
Province
Semnan
Postal code
7157759318
Phone
+98 71 3740 8566
Email
soheil.rad2019@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
No
Proportion provided by this source
1
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
Islamic Azad University
Full name of responsible person
Nasrin Razavianzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Hesabi avenue
City
Shahrood
Province
Semnan
Postal code
7157759318
Phone
+98 71 3740 8566
Email
soheil.rad2019@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Nasrin Razavianzadeh

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

Street address
Hesabi avenue

City
Shahrood

Province
Semnan

Postal code
7157759318

Phone
+98 71 3740 8566

Email
soheil.rad2019@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Soheil shahramirad

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Education

Street address
Hesabi avenue

City
Shahrood

Province
Semnan

Postal code
۷۱۵۷۷۵۹۳۱۸

Phone
+98 71 3740 8566

Email
soheil.rad2019@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no plan to share individual participant data (IPD) due to concerns regarding participant privacy and confidentiality, as well as restrictions imposed by the institutional ethics committee at Khatam Hospital. The study team prioritizes protecting sensitive participant information, and only aggregated data will be published to ensure compliance with ethical and regulatory requirements.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Title: Lipid and Glycemic Control Data in Patients with Dyslipidemia and Type 2 Diabetes Mellitus Details: The dataset includes de-identified individual participant data from a clinical trial conducted at Khatam Hospital, Shahrood, Iran (September 2024–December 2025). It encompasses lipid profile parameters (TG, TC, LDL-C, HDL-C), liver function tests (AST, ALT), creatinine levels, and primary outcome data (e.g., LDL-C reduction) collected at baseline and after 12 weeks. Only de-identified data will be shared to protect participant privacy. Study protocols and statistical analysis plans are also available

When the data will become available and for how long
Timeframe: Data and documents will be available starting 6 months after the publication of primary study results, with access available until December 2030.

To whom data/document is available
The dataset includes de-identified individual participant data from a clinical trial conducted at Khatam Hospital, Shahrood, Iran (September 2024–December 2025). It encompasses lipid profile parameters (TG, TC, LDL-C, HDL-C), liver function tests (AST, ALT), creatinine levels, and primary outcome data (e.g., LDL-C reduction) collected at baseline and after 12 weeks. Only de-identified data will be shared to protect participant privacy. Study protocols and statistical analysis plans are also available.

Under which criteria data/document could be used
Requests should be submitted via email to the principal investigator, Dr. Nasrin Razavianzadeh]. Alternatively, contact the Khatam Hospital Research Office at khatam hospital, phone: 09367662048 The principal investigator or research office staff will respond to inquiries.

From where data/document is obtainable
Applicants must submit a formal request including a research proposal outlining the study objectives, methodology, and data use plan. The request will be reviewed by the study’s data access committee within 4 weeks. If approved, a data sharing agreement will be sent for signing. Upon agreement, de-identified data or documents will be provided via a secure online platform within 2 weeks. The entire process typically takes 6–8 weeks from submission to data receipt.

What processes are involved for a request to access

data/document

Applicants must submit a formal request including a research proposal outlining the study objectives, methodology, and data use plan. The request will be reviewed by the study's data access committee within 4 weeks. If approved, a data sharing agreement will be sent for signing. Upon agreement, de-identified data or documents will be provided via a secure online platform within 2 weeks. The entire process typically takes 6–8 weeks from submission to data receipt.

Comments