

# 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  $\geq 6.5\%$ , fasting plasma glucose  $\geq 126$  mg/dL, or 2-hour plasma glucose  $\geq 200$  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/m<sup>2</sup>. 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/m<sup>2</sup>. ·

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 m<sup>2</sup>. · 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 Group Patients 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 Group Patients 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**