Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Comparative study of the lipids effects of telmisartan and valsartan in patients with STEMI

Protocol summary

Study aim
To help determine the more effective drug between telmisartan and valsartan in the acute phase of STEMI, in order to select a more standardized and guideline-based treatment to improve patient

Design
This study is a single-center, parallel-group, active-controlled randomized clinical trial in 248 patients with acute ST-segment elevation myocardial infarction. Eligible patients will be randomly assigned one-to-one to receive telmisartan or valsartan. Randomization will be performed using a simple randomization list generated by the computer software Random.org,

Settings and conduct
This study is a single-center randomized clinical trial conducted at Bu-Ali-Sina Teaching and Therapeutic Hospital in Qazvin. Eligible patients with acute myocardial infarction with ST-segment elevation will be enrolled after confirming the diagnosis based on clinical criteria, electrocardiography, and cardiac enzymes, and after obtaining written informed consent. .

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 30 to 80 years with acute ST-segment elevation myocardial infarction (STEMI) based on clinical criteria, electrocardiography, and cardiac enzymes Indications for the use of renin-angiotensin system inhibitors (ACE inhibitors or angiotensin receptor blockers) .... Exclusion criteria Myocardial infarction with cardiogenic shock or symptomatic heart failure ...

Intervention groups
Intervention group 1 (Telmisartan) . Active control group (Valsartan)

Main outcome variables
Changes in lipid profile including total cholesterol, LDL-C, HDL-C, and triglycerides; changes in metabolic markers related to blood sugar including FBS and HbA1c; changes in left ventricular function based on ejection fraction (LVEF)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251213068301N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date
2025-12-25, 1404/10/04

Registrant information

Name
Mohammad Taghipoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3337 7035

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mohamad.taghipoor70@gmail.com

Recruitment status
recruiting

Funding source

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

Expected recruitment end date
2027-03-11, 1405/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparative study of the lipids effects of telmisartan and valsartan in patients with STEMI

Public title
Comparative study of the lipids effects of telmisartan and valsartan in patients with STEMI
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with STEMI Abdicación clases 1 for ACE OR ARB
Exclusion criteria:
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **248**
Randomization (investigator's opinion)
Randomized
Randomization description
This study was an open-label randomized clinical trial
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
boali
City
qazvin
Province
Qazvin
Postal code
3481754153
Approval date
2025-12-13, 1404/09/22
Ethics committee reference number
IR.QUMS.REC.1404.356

Health conditions studied

1

Description of health condition studied
Myocardial infarction (MI)
ICD-10 code
I21.01
ICD-10 code description
ST elevation (STEMI) myocardial infarction

Primary outcomes

1

Description
Lipid profile including total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides
Timepoint
3 m after starting the medication
Method of measurement
Blood sampling and serum testing with a standard blood biochemistry analyzer

2

Description
Serum creatinine level and glomerular filtration rate (GFR) indicating kidney function.
Timepoint
Before starting the medication and 3 m after starting the medication
Method of measurement
Blood sample and serum analysis with standard device

Secondary outcomes

1

Description
Systolic and diastolic blood pressure of patients
Timepoint
Before starting the medication, 4 weeks after starting the medication
Method of measurement
Standard mercury sphygmomanometer

2

Description
Body mass index (BMI) of patients
Timepoint
Before starting the medication, 4 weeks after starting the medication
Method of measurement
Measuring height and weight with a standard scale and tape measure

3

Description

Fasting blood glucose level

Timepoint

Before starting the medication, 4 weeks after starting the medication

Method of measurement

Blood sample and serum test with standard blood biochemistry analyzer

4

Description

Adverse drug reactions

Timepoint

During the treatment period

Method of measurement

Questionnaire and clinical interview

Intervention groups

1

Description

Intervention group: Telmisartan

Category

Treatment - Drugs

2

Description

Intervention group: Valsartan

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Bu Ali Sina Educational and Medical Center

Full name of responsible person

Majid Hajikarimi

Street address

Bu Ali Street, corner of Bu Ali Crossroads

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majidhajikarimi57@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr mehrdel

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Boali hospital

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mohamad.taghipoor70@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mohamad taghi pour

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific

inquiries

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Position
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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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Document / Data Title Deidentified Data of Patients with STEMI in the Telmisartan and Valsartan Comparison Trial Document / Data Details Participant personal data including baseline demographic information, baseline clinical characteristics, metabolic laboratory parameters (lipid profile and blood glucose indicators), and primary outcome variables of the study will be potentially shareable after all identifying and de-identifying information has been removed. Data sharing will be limited to data related to the primary and secondary outcomes of the study, and raw patient identifying information (including name, national code, case number, or contact information) will not be provided at any stage. Access to data will only be possible upon written request from researchers and after approval by the investigator responsible for the study.

When the data will become available and for how long
De-identified participant data will be available to eligible researchers for 6 months after the publication of the main study results and for 5 years.

To whom data/document is available
De-identified data of participants will be accessible to eligible researchers. These individuals include researchers working in academic and research institutions as well as independent researchers, provided that they submit a written request and their research purpose is approved by the investigator responsible for the study. Access to data for commercial or industrial purposes is not possible without the written consent of the investigator responsible for the study.

Under which criteria data/document could be used
De-identified data and study documentation are authorized for use only for research and scientific analyses related to the metabolic effects of telmisartan and valsartan in patients with STEMI. Requests for access to data must be made in writing, stating the specific research purpose, and will be made available upon approval by the study investigator. Use of data for commercial, promotional, or any non-scientific publication is prohibited. Applicant researchers are required to keep all data de-identified and confidential after use and to cite any publication of results to the original study.

From where data/document is obtainable
All requests for access to de-identified data and study documentation should be sent to the study investigator: Name and title: Dr. Majid Haji Karimi (principal investigator) Center: Bu-Ali Sina Educational and Therapeutic Center, Qazvin, Iran Postal address: Iran-Qazvin Province-Qazvin City-Bu-Ali St.-Bu-Ali Sina Educational and Therapeutic Center Qazvin Email: majidhajikarimi57@gmail.com Phone: 00982833332935 Fax: 00982833326033 Priority of response is as follows:

Send written request via email Call or fax for further coordination Send postal letter if necessary Applicants are required to state their research objective and the type of analysis desired in the request. All requests will be authorized for scientific and research use after review and approval by the study investigator.

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

Submitting a written request: The applicant must send an email or formal letter to the study investigator including the research objective, the type of analysis desired, and their contact information. Reviewing the request: The study investigator reviews the request and ensures that the proposed use is consistent with the scientific objectives of the study and complies with the principles of research ethics. Approval and conclusion of the agreement: If approved, the applicant is required to sign a confidentiality agreement and comply with the terms of use of data and documentation. Data preparation: De-identified data and documentation limited to the primary and secondary outcomes are prepared. Data delivery: Data is provided to the applicant via secure email, encrypted file, or secure download link. Duration: The entire process from the time the request is submitted to the time the data is received usually takes about 4 to 6 weeks, depending on the volume of the request and the time it takes the study investigator to review it.

Comments