

# 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)

##### Phone

+98 28 3337 7035

##### Email address

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 |                                                                                             |
| <b>Public title</b>                                                                         | Comparative study of the lipids effects of telmisartan and valsartan in patients with STEMI |
| <b>Purpose</b>                                                                              | Treatment                                                                                   |
| <b>Inclusion/Exclusion criteria</b>                                                         |                                                                                             |
| <b>Inclusion criteria:</b>                                                                  | patients with STEMI Abdicación clases 1 for ACE OR ARB                                      |
| <b>Exclusion criteria:</b>                                                                  |                                                                                             |
| <b>Age</b>                                                                                  | From <b>30 years</b> old to <b>80 years</b> old                                             |
| <b>Gender</b>                                                                               | Both                                                                                        |
| <b>Phase</b>                                                                                | 4                                                                                           |
| <b>Groups that have been masked</b>                                                         | No information                                                                              |
| <b>Sample size</b>                                                                          | Target sample size: <b>248</b>                                                              |
| <b>Randomization (investigator's opinion)</b>                                               | Randomized                                                                                  |
| <b>Randomization description</b>                                                            | This study was an open-label randomized clinical trial                                      |
| <b>Blinding (investigator's opinion)</b>                                                    | Not blinded                                                                                 |
| <b>Blinding description</b>                                                                 |                                                                                             |
| <b>Placebo</b>                                                                              | Not used                                                                                    |
| <b>Assignment</b>                                                                           | Parallel                                                                                    |
| <b>Other design features</b>                                                                |                                                                                             |
| <b>Secondary Ids</b>                                                                        | empty                                                                                       |
| <b>Ethics committees</b>                                                                    |                                                                                             |
| <b><u>1</u></b>                                                                             |                                                                                             |
| <b>Ethics committee</b>                                                                     |                                                                                             |
| <b>Name of ethics committee</b>                                                             | Ethics Committee of Qazvin University of Medical Sciences                                   |
| <b>Street address</b>                                                                       | boali                                                                                       |
| <b>City</b>                                                                                 | qazvin                                                                                      |
| <b>Province</b>                                                                             | Qazvin                                                                                      |
| <b>Postal code</b>                                                                          | 3481754153                                                                                  |
| <b>Approval date</b>                                                                        | 2025-12-13, 1404/09/22                                                                      |
| <b>Ethics committee reference number</b>                                                    | IR.QUMS.REC.1404.356                                                                        |

|                                                |                                                                                                                             |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Health conditions studied</b>               |                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                             |
| <b>Description of health condition studied</b> | Myocardial infarction (MI)                                                                                                  |
| <b>ICD-10 code</b>                             | I21.01                                                                                                                      |
| <b>ICD-10 code description</b>                 | ST elevation (STEMI) myocardial infarction                                                                                  |
| <b>Primary outcomes</b>                        |                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                             |
| <b>Description</b>                             | Lipid profile including total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides |
| <b>Timepoint</b>                               | 3 m after starting the medication                                                                                           |
| <b>Method of measurement</b>                   | Blood sampling and serum testing with a standard blood biochemistry analyzer                                                |
| <b><u>2</u></b>                                |                                                                                                                             |
| <b>Description</b>                             | Serum creatinine level and glomerular filtration rate (GFR) indicating kidney function.                                     |
| <b>Timepoint</b>                               | Before starting the medication and 3 m after starting the medication                                                        |
| <b>Method of measurement</b>                   | Blood sample and serum analysis with standard device                                                                        |
| <b>Secondary outcomes</b>                      |                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                             |
| <b>Description</b>                             | Systolic and diastolic blood pressure of patients                                                                           |
| <b>Timepoint</b>                               | Before starting the medication, 4 weeks after starting the medication                                                       |
| <b>Method of measurement</b>                   | Standard mercury sphygmomanometer                                                                                           |
| <b><u>2</u></b>                                |                                                                                                                             |
| <b>Description</b>                             | Body mass index (BMI) of patients                                                                                           |
| <b>Timepoint</b>                               | Before starting the medication, 4 weeks after starting the medication                                                       |
| <b>Method of measurement</b>                   | Measuring height and weight with a standard scale and tape measure                                                          |
| <b><u>3</u></b>                                |                                                                                                                             |
| <b>Description</b>                             |                                                                                                                             |

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  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
3413786165  
**Phone**  
+98 28 3333 2930  
**Email**  
majidhajikarimi57@gmail.com

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Qazvin University of Medical Sciences

#### **Full name of responsible person**

Dr mehrdel

#### **Street address**

Boali hospital

#### **City**

Qazvin

#### **Province**

Qazvin

#### **Postal code**

3481754153

#### **Phone**

+98 28 3333 2930

#### **Email**

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

#### **Street address**

Boali hospital

#### **City**

Qazvin

#### **Province**

Qazvin

#### **Postal code**

3413786165

#### **Phone**

+98 28 3333 2930

#### **Email**

mohamad.taghipoor70@gmail.com

### Person responsible for scientific

## **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

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**Email**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Mohammad Taghipoor

**Position**

Cardiology rezident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

Boali

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**Province**

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**Postal code**

3413786165

**Phone**

+98 28 3337 7035

**Fax**

**Email**

mohahmad.taghipoor70@gmail.com

## **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**