

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### **Efficacy and safety endpoints of Ranolazine in comparison with conventional therapy in reduction of HbA1c percentage in type 2 diabetic patients with ischemic heart disease**

#### **Protocol summary**

##### **Study aim**

An useful trial to change the protocol of using Ranolazine consumption in diabetic patients with CAD

##### **Design**

Two arm parallel group randomized trial with none-blinded postoperative care and outcome assessment of 60 patients

##### **Settings and conduct**

Rajaie cardiovascular, medical and research center, Valiasr Avenue, Tehran, Iran

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: HbA1c more than 6.5%, Age more than 50 year, both genders with diabetes mellitus and CAD. CSA at least 3 months triggered by physical effort and relieved by rest and/or sublingual nitroglycerin. CAD documented by one or more of the following: Angiography evidence of more than 50% stenosis of one or more coronary arteries, History of MI, Cardiac imaging or exercise test diagnostic for CAD. Treatment with up to 2 anti-anginal therapies at a stable dose for at least 2 weeks before starting the trial. T2DM patients who use Metformin and Gliclazide. Exclusion criteria: New York Heart Association Class III and IV. Acute coronary syndrome in the prior 2 months or planned for coronary revascularization. Stroke or transient ischemic attack within 6 months prior. QTc more than 500 ms. Systolic blood pressure more than 180, diastolic blood pressure more than 110 mmHg. Liver cirrhosis. Prior treatment with CYP 3A4 inhibitors or P GlyP inductors. Treatment with anti arrhythmic medicine class II and III. Alcohol consumption or drug users. Simvastatin consumption.

##### **Intervention groups**

Control group who takes nitroglycerin and metformin and glyclazide and in other group ranolazine added and nitroglycerin consumption discontinued

##### **Main outcome variables**

Reduction of HbA1c

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20161026030511N3**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

##### **Registration date**

2018-12-23, 1397/10/02

##### **Registrant information**

##### **Name**

bahram fariborz farsad

##### **Name of organization / entity**

Rajaei Cardiovascular, Medical & Research Center

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 21 22139

##### **Email address**

ffarsad@rhc.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Samin daroo company

##### **Expected recruitment start date**

2016-06-21, 1395/04/01

##### **Expected recruitment end date**

2016-12-21, 1395/10/01

##### **Actual recruitment start date**

2016-06-21, 1395/04/01

##### **Actual recruitment end date**

2016-12-21, 1395/10/01

**Trial completion date**

2017-02-23, 1395/12/05

**Scientific title**

Efficacy and safety endpoints of Ranolazine in comparison with conventional therapy in reduction of HbA1c percentage in type 2 diabetic patients with ischemic heart disease

**Public title**

Efficacy of Ranolazine in reduction of blood sugar in type 2 diabetic patients with ischemic heart disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

HbA1c more than 6.5%, Age more than 50 year, both genders with diabetes mellitus and coronary artery disease (CAD) Experiencing chronic stable angina for at least 3 months triggered by physical effort and relieved by rest and/or sublingual nitroglycerin CAD documented by one or more of the following: Angiography evidence of more than 50% stenosis of one or more coronary arteries, History of MI, cardiac imaging or exercise test diagnostic for CAD Treatment with up to 2 anti-anginal therapies at a stable dose for at least 2 weeks before starting the trial T2DM patients who use Metformin and Gliclazide

**Exclusion criteria:**

New York Heart Association class III and IV Acute coronary syndrome in the prior 2 months or planned for coronary revascularization Stroke or transient ischemic attack within 6 months prior QTc more than 500 ms Systolic blood pressure more than 180, diastolic blood pressure more than 110 mmHg Liver cirrhosis Prior treatment with CYP 3A4 inhibitors or P GlyP inductors Treatment with anti arrhythmic medicine class II and III Alcohol consumption or drug users Simvastatin consumption

**Age**

From **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description****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 Shahid Beheshti University of Medical Sciences

**Street address**

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Valiasr Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

6153- 14155

**Approval date**

2015-11-30, 1394/09/09

**Ethics committee reference number**

IR.SBMU.PHNM.1394.308

**Health conditions studied****1****Description of health condition studied**

Diabetes mellitus

**ICD-10 code**

E11.0

**ICD-10 code description**

Type 2 diabetes mellitus with hyperosmolarity

**2****Description of health condition studied**

Stable angina

**ICD-10 code**

I20.8

**ICD-10 code description**

Other forms of angina pectoris

**Primary outcomes****1****Description**

Percentage of HbA1c

**Timepoint**

Per month

**Method of measurement**

Blood test Hitachi 911 automatic analyzer

**Secondary outcomes****1****Description**

Reduction of using sublingual nitroglycerin per week

**Timepoint**

Weekly

**Method of measurement**

Patient report

**Intervention groups****1****Description**

intervention group: treatment with Ranolazine (Ranexa)  
1000 mg orally 2 times a day for 8 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: continued their conventional therapy  
Nitroglycerin 2.6 mg orally twice a day

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rajaie Cardiovascular Medical and Research Center

**Full name of responsible person**

Bahram Fariborz Farsad

**Street address**

Valiasr Ave Niayesh Intersection

**City**

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**Postal code**

1991953381

**Phone**

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**Email**

ffarsad@yahoo.com

**Web page address**

http://www.rhc.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Samin Daroo Company

**Full name of responsible person**

Dr Bahram Fariborz Farsad

**Street address**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Samin Daroo Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Rajaie cardiovascular, medical and research center

**Full name of responsible person**

Bahram Fariborz Farsad

**Position**

Clinical pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Bahram Fariborz Farsad

**Position**

Clinical pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Email**

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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**

Not applicable

**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**

Not applicable

**Title and more details about the data/document**

The data will be sent by email to those who are interested after the article published

**When the data will become available and for how long**

6 month after publishing the article

**To whom data/document is available**

Pharmacists and medical doctors

**Under which criteria data/document could be used**

Only for continue the researches which is suggested in the article

**From where data/document is obtainable**

Dr Farsad, Rajaie cardiovascular, medical and research center

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

send request by email

**Comments**

not available