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 Ranolazin 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 nitroclycerin 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 ll and lll 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

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 23921

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

Valiasr Ave Niayesh Intersection

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 23921

Email

ffarsad@yahoo.com

Web page address

http://www.rhc.ac.ir

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

Street address

Valiasr Ave., Niayesh Intersection

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 2266 3310

Fax

Email

ffarsad@yahoo.com

Web page address

http://www.rhc.ac.ir

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
Medical Pharmacy
Street address
Valiasr Ave., Niayesh Intersection
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 2266 3310
Fax
Email
ffarsad@yahoo.com
Web page address
http://www.rhc.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Bahram Fariborz Farsad
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Valiasr Ave., Niayesh Intersection
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 2266 3310
Fax
Email
ffarsad@yahoo.com
Web page address
http://www.rhc.ac.ir

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