

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effectiveness of over-sized stenting versus conventional stenting in patients undergoing primary percutaneous coronary intervention

Protocol summary

Study aim

Evaluation of over-size stenting in patient with acute myocardial infarction undergoing primary percutaneous coronary intervention

Design

Single blinded parallel group randomized controlled trial

Settings and conduct

The trial will be held in a hospital setting. Patients will be randomized via central web based method into the interventional group (oversized stenting) and control group (conventional stenting) Patients will be blinded. Stenting outcome after the procedure and 6 months later will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with acute ST elevation myocardial infarction who undergoing primary percutaneous coronary intervention. Exclusion criteria: Primary percutaneous coronary intervention without stenting, on saphenus vein graft, on stent thrombosis and in rescue setting and unable to measure ST resolution.

Intervention groups

In interventional group, after diagnostic angiography, intracoronary nitroglycerin will be injected and infarcted vessel size in the proximal and distal section was measured by quantitative coronary analysis system . Then considering average of vessel diameter and operator decision the size of stent was chosen and 10% oversizing was done. In control group, after after diagnostic angiography, intracoronary nitroglycerin will be injected and infarcted vessel size in the proximal and distal section was measured by quantitative coronary analysis system . Then considering average of vessel diameter and operator decision the size of stent was chosen but it will not be oversized.

Main outcome variables

primary outcome: cardiac enzyme, ST-segment

resolution, No-reflow phenomenon, Hospital stay days
Secondary outcome: Target vessel revascularization, Target lesion, revascularization, Reinfarction, All cause mortality, Cardiovascular mortality Congestive heart failure, Cerebrovascular accident

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190411043242N1**

Registration date: **2019-08-29, 1398/06/07**

Registration timing: **retrospective**

Last update: **2019-08-29, 1398/06/07**

Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

Ata Firouzi

Name of organization / entity

Shahid Rajaei Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

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+98 21 23921

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01
Expected recruitment end date
 2019-03-19, 1397/12/28
Actual recruitment start date
 2018-09-23, 1397/07/01
Actual recruitment end date
 2019-03-19, 1397/12/28
Trial completion date
 2019-09-22, 1398/06/31

Scientific title
 Comparison of the effectiveness of over-sized stenting versus conventional stenting in patients undergoing primary percutaneous coronary intervention

Public title
 Over-sized stenting in primary percutaneous coronary intervention

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with acute myocardial infarction with >0.1 mV ST-segment elevation from baseline in at least two contiguous leads on the 12-lead electrocardiogram who were candidate for primary percutaneous intervention
Exclusion criteria:
 Primary percutaneous coronary intervention without stenting Primary percutaneous coronary intervention of saphenus vein graft Rescue Primary percutaneous coronary intervention stent thrombosis myocardial infarction Electrocardiogram data inadequate to measure ST resolution

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **94**
 Actual sample size reached: **94**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Only participant in this study were be blinded

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rajaie Cardiovascular, Medical & Research Center

Street address

Hashemi Rafsanjani highway, Valiasr street

City

Tehran

Province

Tehran

Postal code

199691151

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.RHC.REC.1398.020

Health conditions studied

1

Description of health condition studied

Patient with acute myocardial infarction undergoing primary coronary angioplasty

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

cardiac enzyme level

Timepoint

twelve hours after procedure

Method of measurement

Lab kit

2

Description

ST segment resolution

Timepoint

60 minute after procedure

Method of measurement

electrocardiogram

3

Description

No Reflow phenomenon

Timepoint

after stent implantation

Method of measurement

angiography

4

Description

hospital stay

Timepoint

hospital course

Method of measurement

patient profile

Secondary outcomes

1

Description

target vessel revascularization

Timepoint

six months after intervention

Method of measurement

Medical record

2

Description

Reinfarction

Timepoint

six months after intervention

Method of measurement

Medical record

3

Description

cardiovascular death

Timepoint

six months after intervention

Method of measurement

Medical record

4

Description

all cause death

Timepoint

six months after intervention

Method of measurement

Medical record

5

Description

congestive heart failure

Timepoint

six months after intervention

Method of measurement

Medical record

6

Description

cardiovascular accident

Timepoint

six months after intervention

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: oversized stenting. In interventional group, after diagnostic angiography, intracoronary nitroglycerin will be injected and infarcted vessel size in the proximal and distal section was measured by quantitative coronary analysis system . Then considering average of vessel diameter and operator decision the size of stent was chosen and 10% oversizing was done.

Category

Treatment - Other

2

Description

Control group: Nonoversized stenting. In control group, after after diagnostic angiography, intracoronary nitroglycerin will be injected and infarcted vessel size in the proximal and distal section was measured by quantitative coronary analysis system . Then considering average of vessel diameter and operator decision the size of stent was chosen but it will not be oversized.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rajaie cardiovascular medical and research center

Full name of responsible person

Seyyed Ali Banifateme

Street address

Hashemi Rafsanjani highway, Valiasr street

City

Tehran

Province

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Phone

+98 21 2266 3249

Email

Banifateme_cardio@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Rajaie Cardiovascular Medical and Research center

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

Rajaie cardiovascular medical and research center

Full name of responsible person

Seyyed Ali Banifatemeh

Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

Firouzi Ata

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Seyyed Ali Banifatemeh

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

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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

Unavailability of resources

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available