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

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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 sternting. 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 Banifatemeh
Street address
Hashemi Rafsanjani highway, Valiasr street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rajaie cardiovascular medical and research center
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Seyyed Ali Banifatemeh
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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
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Person responsible for scientific inquiries

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Assistant professor
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Person responsible for updating data

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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