Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Intracoronary injection of integrilin in patients with acute anterior STEMI with primary angioplasty and its outcome

Protocol summary

Study aim

Evaluation of intracranial clinical outcome of intracoronary injection of integriline in primary angioplasty in patients with acute anterior STEMI

Design

Clinical trial with control group, sample size in each group of 50 people, with parallel groups, double blind, randomized

Settings and conduct

In this study, 50 patients with acute anterior MI, referred to the Emergency Department of the Madani Hospital for less than 12 hours, are selected as case group and 50 similar patients as control group. Patients with suitable coronary anatomy for PCI will be selected. Patients with cardiogenic shock, or coronary bypass candidates, are excluded . Patients will also be selected when TIMI FLOW =0. The case group, after applying the guiding catheter, and after passing the 0.014 inch guide wire and before passing the balloon, intra coronary of Integrilin based on the weight of the patient will injected in coronary artery (LAD)) .The control group will receive an equivalent volume of N / S and heparin. After performing PPCI, patients will be compared in terms of complications of MI within the hospital for bleeding complications ، ،death, heart failure and cardiac enzyme levels in the two groups. In this study, the researcher and analyzer will be blind.

Participants/Inclusion and exclusion criteria

Patients with suitable coronary anatomy for PCI will be selected. Patients with cardiogenic shock, or coronary bypass candidates, are excluded . Patients will also be selected when TIMI FLOW =0

Intervention groups

The case group, after applying the guiding catheter, and after passing the 0.014 inch guide wire and before passing the balloon, intra coronary of Integrilin based on the weight of the patient will injected in coronary artery (LAD)) .The control group will receive an equivalent volume of N / S and heparin.

Main outcome variables

Bleeding rate, Heart failure, Mortality, Cardiac enzyme levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140512017666N3**
Registration date: **2019-11-26, 1398/09/05**
Registration timing: **prospective**

Last update: **2019-11-26, 1398/09/05**
Update count: **0**

Registration date

2019-11-26, 1398/09/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3880

Email address

separham@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Intracoronary injection of integrilin in patients with acute anterior STEMI with primary angioplasty and its outcome

Public title
Intracoronary injection of integrilin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
TIMI FLOW equals zero Acute Ant MI patient admitted to civil hospital emergency room under 12 hours Ages over 16 years
Exclusion criteria:
Patients with coronary bypass candidiasis Patients resuscitated with cardiogenic shock
Age
From **16 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked Randomization" is used to allocate samples in control and intervention groups with 1:1 ratio.Random numbers are generated by RANDLIST software vesion 1.5 in 17 bocks with block size of 10.
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 Tabriz University of Medical Sciences
Street address
Cardiology Department Office, Madani Hospital, Daneshgah st.Tabriz,Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665935
Approval date
2019-10-15, 1398/07/23
Ethics committee reference number
IR.TBZMED.REC.1398.730

Health conditions studied

1

Description of health condition studied
STEMI
ICD-10 code
Z98.6
ICD-10 code description
Angioplasty status

Primary outcomes

1

Description
Cardiac enzyme levelsCardiac enzyme levels
Timepoint
It is measured 6 times at 4 hour intervals.
Method of measurement
PPCI

2

Description
Mortality
Timepoint
1, 6 and 12 months after discharge
Method of measurement
Questionaire

3

Description
STEMI with primary angioplasty
Timepoint
Hospitalization Period
Method of measurement
ECG and enzyme

4

Description
In-hospital bleeding
Timepoint
Hospitalization Period
Method of measurement
Clinical examination and laboratory findings

5

Description
Heart failure

Timepoint
1, 6 and 12 months after discharge
Method of measurement
Eco cardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after applying the guiding catheter, and after passing the 0.014 inch guide wire and before passing the balloon, intra coronary of Integrilin based on the weight of the patient will injected in coronary artery (LAD))
Category
Treatment - Drugs

2

Description
Control group: The control group will receive an equivalent volume of N / S and heparin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Ahmad Separham
Street address
Iran,Tabriz,Daneshgah st,Shahid Madani Hospital,
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 51 6661 4756
Email
Madanihearthosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolgasem Jouiban
Street address
Tabriz university of medical sciences research and technology deputy,Tabriz,Iran
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5165665935
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+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ahmad Separham
Position
Associate professore
Latest degree
Specialist
Other areas of specialty/work
Cardiology
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Daneshgah street-Madani heart center-cardiology department,Tabriz,Iran
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available