

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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 version 1.5 in 17 blocks 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 levels Cardiac 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**

Questionnaire

**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

Madaniheartosp@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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665935

##### Phone

+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

##### Street address

Daneshgah street-Madani heart center-cardiology department,Tabriz,Iran

##### City

Tabriz

##### Province

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##### Postal code

5166614756

##### Phone

+98 41 3337 3903

##### Email

separham@tbzmed.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ahmad Separham

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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