

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of Clinical efficacy and safety of injection of bovine thrombin and compression method in femoral pseudoaneurysm of patients undergoing PCI intervention at Rajaie Heart Center

Protocol summary

Summary

We studied efficacy and success rate of thrombin subcutaneous injection under ultrasound with compression method in the treatment of pseudoaneurysm and evaluated thrombin injection effects on coagulation parameters. 40 patients aged 15 to 85 years, after intervention with femoral pseudoaneurysm were randomly assigned into two groups to treat either under compression method or by subcutaneous injection under ultrasound thrombin. Thrombin vials were reconstituted with 0.9% normal saline in hospital pharmacy under laminar air flow. Pseudoaneurysm size, neck length and width, thrombin dose, thrombosis time, outcome of therapy and complications were recorded. Duplex sonography at 0 and 24 hours afterward were performed. Injection was stopped when no further flow was detected in pseudoaneurysm. Thromboplastin time and quick test (prothrombin time) were checked before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806112363N4**
Registration date: **2010-09-23, 1389/07/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-23, 1389/07/01

Registrant information

Name

Fariborz Farsad

Name of organization / entity

Shahid Rajaie Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2266 3310

Email address

farsad@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Rajaie Heart Center

Expected recruitment start date

2009-10-01, 1388/07/09

Expected recruitment end date

2010-05-01, 1389/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Clinical efficacy and safety of injection of bovine thrombin and compression method in femoral pseudoaneurysm of patients undergoing PCI intervention at Rajaie Heart Center

Public title

Comparison of Clinical efficacy and safety of injection of bovine thrombin and compression method in femoral pseudoaneurysm of patients undergoing PCI intervention at Rajaie Heart Center

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 15-85 years old, presence of

vascular disease, presence of bleeding because of femoral pseudoaneurysm Exclusion criteria: pregnancy, breast feeding, past history of bleeding with thrombin

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Shahid Rajaie Heart Center

Street address

Valiasr ave.

City

Tehran

Postal code

1996911151

Approval date

empty

Ethics committee reference number

6729

Health conditions studied

1

Description of health condition studied

Femoral pseudoaneurysm

ICD-10 code

Y84.0

ICD-10 code description

Cardiac catheterization

Primary outcomes

1

Description

Thrombosis time

Timepoint

At the time of treatment

Method of measurement

duplex sonography

2

Description

pseudoaneurysm size

Timepoint

At the time of treatment

Method of measurement

duplex sonography

3

Description

neck length and width

Timepoint

At the time of treatment

Method of measurement

duplex sonography

4

Description

outcome of therapy

Timepoint

Baseline and 24 hours afterwards

Method of measurement

duplex sonography

5

Description

complications

Timepoint

Baseline and 24 hours after wards

Method of measurement

duplex sonography

Secondary outcomes

1

Description

coagulatory parameters

Timepoint

once before and after thrombin injection

Method of measurement

PT.PTT

Intervention groups

1

Description

Bovine thrombin, 100-700IU, percutaneous ultrasonographically guided injection, single dose or

multiple doses, in 10-15 seconds

Category

Treatment - Drugs

2

Description

Undergoing compression method in the site of pseudoaneurysm in one or more than one episode, in about 30 minutes by an expert radiologist under sonography guide

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaie Heart Center

Full name of responsible person

Fariborz Farsad

Street address

Valiasr ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaie Heart Center

Full name of responsible person

Fariborz Farsad

Street address

Valiasr ave.

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Rajaie Heart Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Rajaie Heart Center

Full name of responsible person

Maryam Nadermohammadi

Position

pharmacy student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

clinical pharmacist/phd

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty