Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Effects of intravenous and catheter directed thrombolytic therapy with recombinant tissue plasminogen activator (Alteplase) in non-traumatic acute limb ischemia; a randomized double-blind clinical trial

Protocol summary

Summary

The aim of the current study is to evaluate the efficacy of systemic and catheter directed thrombolysis by alteplase in the patients with acute limb ischemia (ALI). We will include 40 patients who are less than 75 years, symptoms duration of 1 to 14 days, ALI of grade IIa and IIb and absence of distal run off. Those with absolute and relative contraindications of thrombolytic therapy will be excluded. Patients will randomly assign to undergo intravenous (0.6 mg per kg over 2 hours) or catheter directed thrombolysis (0.05 mg per kg per hr each 2 hours for 24 hours) with alteplase. The primary endpoint of the study is improvement of clinical status according to Rutherford classification, improvement in pain according to VAS score and improvement in ABI which would be assessed at 1 week, 3, 6 and 12 months after intervention. The secondary endpoint of the study is complete or near complete recanalization of the occluded artery detected by angiography after 1 year of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100719427N1**
Registration date: **2015-07-07, 1394/04/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-07, 1394/04/16

Registrant information

Name

Hassan Ravari

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intravenous and catheter directed thrombolytic therapy with recombinant tissue plasminogen activator (Alteplase) in non-traumatic acute limb ischemia; a randomized double-blind clinical trial

Public title

Intravenous versus catheter directed thrombolytic therapy in non-traumatic acute limb ischemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 75 years; symptoms duration of 1 to 14 days; Acute limb ischemia (ALI) of grade IIa

and IIb according to the Rutherford classification; absence of distal run off in angiography; Ankle-Brachial Index (ABI) less than 0.8 Exclusion criteria: Severe anemia (Hb less than 8 gr per dL); thrombocytopenia (platelet count less than 80000 per micl); low serum fibrinogen (fibrinogen less than 100 mg per dL); severe hypertension (systolic more than 160 mmHg, diastolic more than 100 mmHg); trauma or surgery less than 14 days before intervention; history of subarachnoid hemorrhage; life expectancy of less than 14 months; major internal bleeding less than 6 months before intervention; pregnancy; lumbar puncture 2 weeks before intervention

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

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
Computer-based random digit generator using the admission numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
University street

City
Mashahd

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
89-5511

Health conditions studied

1

Description of health condition studied
Obliteration of lower extremity arteries

ICD-10 code
I79.8

ICD-10 code description
Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere

Primary outcomes

1

Description
Clinical condition

Timepoint
1 week, 1, 3, 6, 12 months

Method of measurement
Rutherford classification; Pain severity measured by VAS; ABI

Secondary outcomes

1

Description
Complete or near complete recanalization of the occluded artery

Timepoint
12 months

Method of measurement
Angiography

Intervention groups

1

Description
Group 1: Alteplase 0.6 mg per kg intravenously in 2 hours. Half of the dosage would be given as bolus dose and the rest would be infused in 2 hours.

Category
Treatment - Drugs

2

Description
Group 2: Alteplase infusion via catheter directed route with 0.05 mg per kg per hour each 2 hours for 24 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital

Full name of responsible person
Hossein Ravari

Street address
Imam Reza square, Ebne Sina street
City
Mashahd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
University street
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Mashahd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Research, Mashhad University of Medical Sciences
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

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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