

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3852 5311

##### Email address

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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

**City**

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**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****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hassan Ravari

**Position**

Associate Professor

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**Web page address****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*