

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of the Therapeutic Role of Prostavasin in Patients with Critical Limb Ischemia

#### Protocol summary

##### Summary

Critical limb ischemia (CLI) is known for ischemic rest pain, ulcer, or gangrene related to arterial occlusive disease. Main purpose of this study was to assess treatment outcomes with prostavasin for patients with critical limb ischemia that are a poor candidate for surgical intervention. 29 patients with CLI who were poor candidates for surgical treatment and cannot tolerate surgery were enrolled in the study. Patients with CLI who have tolerated the surgery, and vascular anatomy were suitable for reconstruction, were excluded from the study. Prostavasin was administered according to the standard 21 days protocol (40mcg of prostavasin daily in 200 ml of physiological saline solution and infusing the resulting solution i.v. over a period of 2 hours). Patients were followed up regarding rest pain, ulcer healing, gangrene, and need to amputation after 2 weeks, 1 month, and 3 months.

#### General information

##### Acronym

epcli

##### IRCT registration information

IRCT registration number: **IRCT201207292220N4**

Registration date: **2012-08-26, 1391/06/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-26, 1391/06/05

##### Registrant information

###### Name

Mohamad Reza Sobhiyeh

###### Name of organization / entity

Shahid Beheshti University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2271 8001

##### Email address

mozafar@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vascular and trauma research center, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2008-09-22, 1387/07/01

##### Expected recruitment end date

2009-10-22, 1388/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Therapeutic Role of Prostavasin in Patients with Critical Limb Ischemia

##### Public title

Effect of prostavasin in patients with limb ischemia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients with rest pain; limb ulcer; gangrene related to arterial occlusive disease who can not tolerate surgery; and vascular anatomy were unsuitable for reconstruction. enrolled in the study.

Exclusion criteria: patients rest pain; limb ulcer; gangrene related to arterial occlusive disease who have tolerated the surgery; and vascular anatomy were suitable for reconstruction, were excluded in the study.

##### Age

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 29

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Shahid Beheshti University of Medical Sciences

**Street address**

Research Deptuy, Shahid Beheshti University of Medical Sciences,Velenjak

**City**

Tehran

**Postal code**

1983969411

**Approval date**

2011-06-21, 1390/03/31

**Ethics committee reference number**

54

**Health conditions studied**

1

**Description of health condition studied**

critical limb ischemia

**ICD-10 code**

I70.2

**ICD-10 code description**

Atherosclerosis of arteries of extremities

**Primary outcomes**

1

**Description**

ankle-brachial index

**Timepoint**

at presentation, 2 weeks, one month, and three months after the administration

**Method of measurement**

color doppler sonography

2

**Description**

rest pain

**Timepoint**

2 weeks, one month, and three months after the administration

**Method of measurement**

history and physical examination

3

**Description**

healing of ulcer

**Timepoint**

2 weeks, one month, and three months after the administration

**Method of measurement**

history and physical examination

4

**Description**

gangrene

**Timepoint**

2 weeks, one month, and three months after the administration

**Method of measurement**

history and physical examination

**Secondary outcomes**

1

**Description**

need to amputation

**Timepoint**

2 weeks, one month, and three months after the administration

**Method of measurement**

history and physical examination

**Intervention groups**

1

**Description**

standard protocol of intravenous administration for 21 days. 40 mcg of prostavasin daily in 200 ml of physiological saline solution and infusing the resulting solution i.v. over a period of 2 hours.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shohadae Tajrish Hospital

**Full name of responsible person**

Lotfollah Zadeh Saran

**Street address**

Shohadae Tajrish Hospital, Tajrish

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Deputy, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr . Rahmati Rodsary Mohammad

**Street address**

Shahid Beheshti University of Medical Sciences, Velenjak

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Deputy, Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Derakhshan Far Amir

**Position**

vascular surgen

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Atqiaee Khashayar

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resident of surgery

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## Person responsible for updating data

### Contact

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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*