

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Outcomes of Venoplasty with stenting in patients with chronic venous insufficiency due to DVT in iliofemoral vein segment

Protocol summary

Study aim

Determining the effectiveness of venoplasty and stent placement in improving the symptoms of chronic thrombosis in the ilio-femoral venous segment.

Design

clinical trial with single group with 30 cases

Settings and conduct

Vascular Surgery Center of Golestan Hospital, Ahvaz

Participants/Inclusion and exclusion criteria

inclusion criteria include patients with symptoms of chronic venous insufficiency and previous proximal deep vein thrombosis. exclusion criteria include definitive diabetic patients and patients with severe CHF or respiratory failure.

Intervention groups

Referred patients with symptoms of chronic venous insufficiency in the lower extremities

Main outcome variables

primary patency of ipsilateral ilio femoral vein segment
0

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201217049747N1**

Registration date: **2021-07-06, 1400/04/15**

Registration timing: **retrospective**

Last update: **2021-07-06, 1400/04/15**

Update count: **0**

Registration date

2021-07-06, 1400/04/15

Registrant information

Name

Saman Ketabchian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 5799

Email address

ketabchian.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2021-06-22, 1400/04/01

Trial completion date

2021-06-22, 1400/04/01

Scientific title

Outcomes of Venoplasty with stenting in patients with chronic venous insufficiency due to DVT in iliofemoral vein segment

Public title

Outcomes of Venoplasty with stenting in patients with chronic venous insufficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

have symptoms of chronic venous insufficiency of lower extremities evidences of previous Iliofemoral segment DVT

Exclusion criteria:

documented diabetic patients significant heart or pulmonary disease

Age

No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

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

Ethics committee of Ahvaz Jondishapoor University of medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Deputy of research and technology.Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.110

Health conditions studied

1

Description of health condition studied

chronic venous insufficiency of lower extremities due to deep vein thrombosis

ICD-10 code

I87.2

ICD-10 code description

Venous insufficiency (chronic) (peripheral)

Primary outcomes

1

Description

patency of illio-femoral vein

Timepoint

primary patency of illio-femoral vein after 3 and 6 months after procedure

Method of measurement

Physical exam and dupler ultrasound

Secondary outcomes

1

Description

rate of edema

Timepoint

before procedure and at third and sixth month after procedure

Method of measurement

Measure the circumference of the middle part of the involved leg

2

Description

Involved leg ulcer condition

Timepoint

before procedure and at third and sixth month after procedure

Method of measurement

Observer assessment of wound condition based on Rutherford classification

3

Description

pain severity score

Timepoint

before procedure and at third and sixth month after procedure

Method of measurement

Score of pain intensity reported by the patient based on NRS criteria

Intervention groups

1

Description

Intervention group: venography and venoplasty and stenting in illio-femoral vein

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Vascular Surgery Center of Golestan Hospital, Ahvaz

Full name of responsible person

Saman Ketabchian

Street address

Khuzestan - Ahvaz - Golestan - Farvardin Blvd

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ketabchian.s@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Armin Mohammadi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Saman Ketabchian

Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Saman Ketabchian

Position

assistance of VASCULAR SERGERY

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Saman Ketabchian

Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be shareable

When the data will become available and for how long

6 months after publication

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

If further analysis is required after submitting the request

From where data/document is obtainable

Director of Vascular Surgery Department, Golestan Hospital, Ahvaz

What processes are involved for a request to access data/document

Submit a request stating the reason and the amount of access required

Comments