Patency, coagulation, and quality of life after deep venous stenting

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To improve our understanding on the etiology of proximal DVTs, to identify risk factors for stent reinterventions and to optimize treatment after a venous stent. To improve patient education and expectation after a venous stent.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON49454

Source
ToetsingOnline

Brief title
Life after a venous stent

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
deep vein thrombosis, thrombosed leg

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: deep venous thrombosis, quality of life, stent patency, venous stent

Outcome measures

Primary outcome

Patency rates of venous stents and predictors for reinterventions or occlusions

Secondary outcomes: prevalence of coagulation disorders in the study population, comparison of coagulation disorders between patients with MT syndrome and right sided or distal DVTs, and quality of life (SF-36 and CIVIQ-20).

Secondary outcome

Prevalence of coagulation disorders in the study population, comparison of coagulation disorders between patients with MT syndrome and right sided or distal DVTs, and quality of life (SF-36 and CIVIQ-20).

Study description

Background summary

Patients with a proximal DVT will develop PTS more often than patients with a distal DVT. Venous stents are found to decrease the risk of PTS in the acute phase, and to lower the symptoms of PTS in the chronic phase. Whether the etiology of a proximal left sided DVT is mainly mechanical (May-Thurner syndrome) or can be addressed to coagulation disorders is unknown. Data are also lacking on risk factors for stent occlusions and quality of life after a venous stent.

Study objective

To improve our understanding on the etiology of proximal DVTs, to identify risk factors for stent reinterventions and to optimize treatment after a venous stent. To improve patient education and expectation after a venous stent.

Study design

Retrospective cohort study and a nested case-control study.

Study burden and risks

No risks are associated with participation. If data on coagulation disorders or imaging is missing, patients are asked to come in once for the collection of a blood sample and/or a duplex ultrasound of the stent. The QOL questionnaires are asked to be filled out once..

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Venous stent placement between 2006 and 2020 at the EMC in the common femoral vein, iliac veins and/or inferior vena cava
- Signed informed consent
- Patients aged 18 years and older
- Sufficient understanding of the Dutch language.

Exclusion criteria

- Non-dedicated venous stents
- No follow-up due to death shortly after stent placement from a malignancy (some stents were used for comfort care)
- Insufficient understanding of the Dutch language
- No informed consent.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2020
Enrollment:	107
Type:	Actual

Ethics review

Approved WMO

Date:	10-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74001.078.20