Stenting of Haemodialysis Acces Trial

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To demonstrate the efficacy of a PTFE covered stent-graft in the prevention of outflow re-stenosis in loop fistula in a prospective trial.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31017

Source
ToetsingOnline

Brief title
SHARE Trial

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
outflow-stenosis, stentgraft

Research involving
Human

Sponsors and support

Primary sponsor: W. L. Gore & Associates Inc, U.S.A.
Source(s) of monetary or material Support: W.L Gore & Associates Inc.

Intervention

Keyword: Haemodialysis, Outflow-stenosis, Stent-Graft, Viabahn

Outcome measures

Primary outcome

Primary endpoints:

Primary patency

Secondary patency

Graft failure

Secondary outcome

Secondary endpoints

Number of radiological re-interventions

Number of Surgical interventions

Graft infection

Study description

Background summary

Haemodialysis access surgery in patients with end-stage renal disease remains challenging due to of a high incidence of complications. Vascular access complications occur in up to 40% of patients with polytetrafluorethylene (ePTFE) grafts within the first 6 months, primarily due to stenosis and thrombosis. Stenosis at the venous anastomosis or in the draining vein may be treated by either angioplasty or surgical intervention. Following angioplasty, however, recurrent stenoses frequently occur. The viabahn stent-graft is a combined ePTFE-Nitinol self-expanding stent-graft preloaded on a catheter-based delivery system. Its flexibility might make the device ideal for the treatment of recurrent outflow stenosis in AV loop-fistula.

Study objective

To demonstrate the efficacy of a PTFE covered stent-graft in the prevention of outflow re-stenosis in loop fistula in a prospective trial.

Study design

The design of this trial is a non-randomized mono-centred prospective intervention (pilot) study.

Intervention

In all patients an angioplasty will be performed with a high-pressure balloon, according to local protocols. If indicated, a cutting balloon may be used.
After dilatation a 5 cm viabahn will be placed.

Study burden and risks

Patients with ePTFE grafts of arteriovenous fistula for hemodialysis purpose receive repeatedly endovasculair treatment because of high incidence of stenosis and thrombosis of these grafts. If this does not suffice, surgery is necessary to maintain access to circulation.
With recurring stenosis of such grafts, a single endovasculair procedure will be performed during which a viabahn stent will be placed. The procedure is not more aggravating than and is as hazardous as standard endovasculair procedures.
During follow-up monthly duplex flow measurements will be performed. This is not invasive and not aggravating for patients It will be performed during regular visits for purpose of hemodialysis.
Six and twelve months after stenting, angiography will be performed for evaluation purpose.

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

Patient of 18 years of age
Patient has a life expectancy of at least 2 years
Patient has re- stenosis within 2 cm from the anastomosis of a loop arterio venous fistula
Signed informed consent

Exclusion criteria

Patient unsuitable for administration of contrast agent
Dementio or atered mental status that would prohibit giving conscious informed consent
Need for adjunctive major surgical procedures within 1 month
Other stenosis

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-12-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Viabahn Endoprothese
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL18459.091.07