A multicentre clinical study of the SWIRLGRAFT ePTFE vascular access graft.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24364

Source
NTR

Brief title
N/A

Health condition

Patients with chronic renal failure who require a prosthetic vascular access for haemodialysis.

Sponsors and support

Primary sponsor: Veryan Medical Ltd
Mr PL Birch
Chief Executive Officer
21 Wilson Street
London EC2M 2TD, UK
Tel. +44 1428 683 351
philip.birch@veryanmed.com
Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

Patency rates.

Secondary outcome

1. Adverse events;

2. Clinical experiences.

Study description

Background summary

In this prospective feasibility study a new vascular access prosthesis, the SWIRLGRAFT, is tested in haemodialysis patients. Based on its helical geometry it is supposed to diminish stenosis at the venous anastomosis resulting in improved patency rates.

Study objective

The helical geometry of this vascular access prosthesis reduces flow stagnation and low shear stress at the venous anastomosis resulting in diminished neointimal hyperplasia.

Study design

N/A

Intervention

Implantation of a SWIRLGRAFT vascular access graft.

This single procedure (60-90 minutes) will be implemented in all participants and the prosthesis will remain in situ.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with chronic renal failure who require prosthetic vascular access for haemodialysis;

2. Informed consent and willing to co-operate;

3. Age 18 or older.

Exclusion criteria

1. Inability to comply with the study follow-up;

2. Known sensitivity to ePTFE;

3. Failure to obtain written informed consent;

4. Patients who have a history of chronic bacterial infection, during the 12 months prior to potential inclusion in the study;

5. Patients with known severe coagulation disorders;

6. Inability to attend all follow up visits;

7. Patients who are on coumarin therapy;

8. Patients who are at risk of steal syndrome due to poor condition of the peripheral arterial vessels, as identified by pre-operative Duplex scan;

9. Pregnancy, intension to become pregnant.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL393
NTR-old	NTR432
Other	: N/A
ISRCTN	ISRCTN11502523

Study results

Summary results
N/A