ISRCTN11502523 https://doi.org/10.1186/ISRCTN11502523

A multicentre clinical study of the SWIRLGRAFT expanded polytetrafluoroethylene vascular access graft

Submission date 27/02/2007	**Recruitment status** No longer recruiting
Registration date 27/02/2007	**Overall study status** Completed
Last Edited 26/03/2021	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL393 (NTR432)

Study information

Scientific Title
A multicentre clinical study of the SWIRLGRAFT expanded polytetrafluoroethylene vascular access graft

Study objectives
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.

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Prospective, parallel group, multicentre feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic renal insufficiency

Interventions
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.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Patency rates

Key secondary outcome(s))

1. Adverse events
2. Clinical experiences

Completion date
31/12/2006

Eligibility

Key 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Total final enrolment
20

Key exclusion criteria
1. Inability to comply with the study follow-up
2. Known sensitivity to expanded Polytetrafluoroethylene (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, intention to become pregnant

Date of first enrolment
01/12/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Veryan Medical Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2007	26/03/2021	Yes	No