

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

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<b>Registration date</b> 27/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/03/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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?
<a href="#">Results article</a>		01/04/2007	26/03/2021	Yes	No