FLOW

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20487

Source
Nationaal Trial Register

Brief title
FLOW

Health condition

Hemodialysis vascular access

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Access-related intervention rate.

Secondary outcome

Complications, medical costs, patient-reported outcomes (SF-VAQ), and the quality of the surveillance program.

Study description

Background summary

The FLOW project evaluates the follow-up of the vascular access for hemodialysis. In current clinical care, vascular access flow volume is periodically assessed to detect and treat asymptomatic stenosis. The FLOW project will determine whether it is safe to abandon this practice of active surveillance. Vascular access stenosis will then be treated only when clinical problems of flow dysfunction occur during hemodialysis.

Study objective

We expect that the access-related intervention rate and medical costs will be reduced by 40% when correction of vascular access stenosis is triggered by clinically apparent access dysfunction rather than by asymptomatic flow reduction detected by surveillance. This would amount to cost savings of 3.0 million euros per year in the Netherlands.
We expect that the rate of access thrombosis will increase no more than 0.5 events per patient-year when correction of vascular access stenosis is triggered by clinically apparent access dysfunction rather than by asymptomatic flow reduction detected by surveillance.

Study design

Patients will be followed up for 2 years for the primary outcome and secondary outcomes. Access-related interventions and complications will be registered prospectively during this time period. Medical costs and patient-reported outcomes will be measured with questionnaires every 3 months. The quality of the surveillance program will be evaluated using data accumulated over the 2-year study period.

Intervention

Intervention group: patients are referred for correction of the underlying stenosis when clinical signs of flow dysfunction are present. These include physical signs, problems during dialysis, or an unexplained, sustained fall in dialysis adequacy.
Comparison group: monthly surveillance of vascular access blood flow volume by ultrasound dilution measurements during hemodialysis sessions. Patients will be referred for correction of the underlying stenosis at an access flow volume <500mL/min, or when clinical signs of flow dysfunction are present.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult patients aged 18 years or older.
2. End-stage renal disease with unlikely recovery of kidney function according to the attending nephrologist.
3. Arteriovenous fistula or arteriovenous graft as hemodialysis vascular access that fulfills both of the following criteria at the time of trial enrollment:
a. Maturation: outflow vein diameter of at least 5mm (not applicable for grafts) and access flow volume of at least 500mL/min; and
b. Functional: the vascular access was cannulated with 2 needles and achieved the prescribed access circuit flow in at least 6 dialysis sessions over the past 30 days.
4. Planning to remain in one of the participating dialysis centers for at least 1 year.

Exclusion criteria

1. Arteriovenous fistulas with multiple venous outflow paths upstream of the cannulation sites, that are not suitable for flow volume measurements using ultrasound dilution (e.g. Gracz fistulas and Ellipsys or WavelinQ endovascular fistulas).
2. Home hemodialysis.
3. Thrombosis of the current vascular access in the past year.
4. Planned access-related intervention.
5. Living donor kidney transplantation or switch to peritoneal dialysis planned within 6 months. 6. Life expectancy of less than 6 months, in the opinion of the attending nephrologist.
7. Unable to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2021
Enrollment:	518
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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	NL9165
Other	METC azM/UM : METC 21-004

Study results