Flow dysfunction of hemodialysis vascular access: a randomized controlled trial on the effectiveness of surveillance of arteriovenous fistulas and grafts

Published: 11-06-2021
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See above.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON54091

Source
ToetsingOnline

Brief title
FLOW

Condition

- Renal disorders (excl nephropathies)
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
end-stage renal disease, Vascular access

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: ZonMW ZE&GG programma

Intervention

Keyword: Hemodialysis, Stenosis, Surveillance, Vascular access

Outcome measures

Primary outcome

The primary outcome is the access-related intervention rate.

Secondary outcome

Secondary outcome measures are complications, medical and societal costs,

patient-reported outcomes, 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. We expect that the intervention rate and medical costs will be reduced by 40% (3.0 million euros per year) when correction of vascular access stenosis is triggered by clinically apparent access dysfunction rather than asymptomatic flow reduction.

Study objective

See above.

Study design

Multicenter randomized controlled trial with 417 patients. Patients will be followed up for 2 to 3 years.
The trial is powered to detect a reduction in the intervention rate of 0.25 per year between study groups in a superiority analysis (this is associated with cost savings of 1 million euros per year). Subgroup analyses of arteriovenous

fistulas and grafts and of successful and failed interventions will be done.

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.

Control 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.

Study burden and risks

Patients randomised to the intervention group may have an increased incidence of vascular access thrombosis. On the other hand, patients randomised to the control group may undergo unnecessary interventions for vascular access stenosis. Study participants will have to fill in questionnaires, which will take approximately 8 hours over the course of the trial.

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

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. Vascular access flow volume of at least 500mL/min; and
b. Functional vascular access: 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. Patients who have single needle hemodialysis for reasons other than vascular access dysfunction (e.g. for nocturnal hemodialysis) but who can be cannulated with 2 needles for flow measurements and fulfill the other requirements for a functional vascular access can be enrolled as well.
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, switch to peritoneal dialysis, or switch to home hemodialysis 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:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2021
Enrollment:	375
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-10-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	17-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-10-2024
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Approved WMO Date:	25-02-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL75845.068.20
Other	NL9165