FLOW

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20487

Bron
Nationaal Trial Register

Verkorte titel
FLOW

Aandoening

Hemodialysis vascular access

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Access-related intervention rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-10-2021
Aantal proefpersonen:	518
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9165
Ander register	METC azM/UM : METC 21-004

Resultaten