Optimizing Access Surgery In Senior hemodialysis patients

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Placement of arteriovenous grafts or permanent central venous catheters results in less access-related interventions, better quality of life, and reduced costs as compared to creation of arteriovenous fistulas in elderly hemodialysis patients.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28751

Bron
Nationaal Trial Register

Verkorte titel
OASIS

Aandoening

End-stage renal disease; hemodialysis; vascular access

Ondersteuning

Primaire sponsor: Academisch Ziekenhuis Maastricht
Overige ondersteuning: Leading the Change

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of access-related interventions required for each person-year of hemodialysis treatment

Toelichting onderzoek

Achtergrond van het onderzoek

The number of elderly hemodialysis patients is growing. Vascular access complications are a major determinant of the quality of life and health care costs for these vulnerable patients. The three different types of vascular access, i.e. autologous arteriovenous fistulas, arteriovenous grafts, and central venous catheters, have never been compared in randomized controlled trials. In this health care evaluation, we will deliver the evidence to determine the optimal strategy for vascular access creation in elderly hemodialysis patients in order to deliver better health care at lower costs.

Doel van het onderzoek

Placement of arteriovenous grafts or permanent central venous catheters results in less access-related interventions, better quality of life, and reduced costs as compared to creation of arteriovenous fistulas in elderly hemodialysis patients.

Onderzoeksopzet

Variable follow-up time with trial closeout when the last patient enrolled has 1 year of follow-up

Onderzoeksproduct en/of interventie

1. Arteriovenous graft implantation
2. Central venous catheter placement
3. Autologous arteriovenous fistula creation (recommended by current guidelines)

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 70 years or older;
2. End-stage renal disease with unlikely recovery of kidney function according to the attending nephrologist;
3. Hemodialysis is the intended long-term modality of treatment for end-stage renal dis-ease;
4. Fit for vascular access surgery as determined by the local multidisciplinary vascular access team;
5. A. Expected to start hemodialysis treatment within 6 months at the time of treatment assignment; or
B. Treated with hemodialysis for 6 months or less at the time of treatment assignment using a tunneled or non-tunneled central venous catheter for vascular access;
6. Planning to remain in one of participating dialysis centers for at least 1 year;
7. Suitable vascular anatomy for all types of vascular access based on duplex ultrasound of the arms, defined as:
• at least one suitable configuration for an arteriovenous fistula using minimal arterial and venous diameters of 2mm for radiocephalic fistulas and 3mm for brachiocephalic and brachiobasilic fistulas;
• at least one suitable configuration for an arteriovenous graft using minimal arterial and venous diameters of 3mm and 4mm, respectively; and
• at least one open internal jugular vein for a central venous catheter.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patent arteriovenous fistula or graft already in place;
2. Prior unsuccessful arteriovenous fistula or graft vascular access surgery;
3. Kidney transplantation planned within 6 months;
4. Metastatic malignancies or other condition associated with a life expectancy of <6 months, in the opinion of the attending nephrologist;
5. Unable to provide informed consent;
6. Dusseux risk score <5, indicating an unusually long life expectancy for elderly patients starting hemodialysis treatment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-12-2019
Aantal proefpersonen:	195
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	04-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54598
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7933
CCMO	NL70385.068.19
OMON	NL-OMON54598

Resultaten