Optimizing Access Surgery In Senior hemodialysis patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28751

Source
Nationaal Trial Register

Brief title
OASIS

Health condition

End-stage renal disease; hemodialysis; vascular access

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Leading the Change

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Patient-reported outcome measures (SF-12 / DSI measured every 3 months and SF-VAQ measured every month until the latest of one year of follow-up or one year of dialysis treatment has been reached), health care costs, access-related complications, days in hospital, and mortality

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2019
Enrollment:	195
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	04-08-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54598
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results