Optimizing Access Surgery In Senior hemodialysis patients

Published: 11-11-2019
Last updated: 21-12-2024

To compare surgical strategies for vascular access creation in elderly hemodialysis patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON54598

Source
ToetsingOnline

Brief title
OASIS

Condition

- Nephropathies
- Vascular therapeutic procedures

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: Leading the Change

Intervention

Keyword: Elderly, Hemodialysis, Vascular access

Outcome measures

Primary outcome

The number of interventions required for each year of hemodialysis treatment

Secondary outcome

Patient-reported outcome measures (SF-12 / DSI / SF-VAQ)

Health care costs

Access-related complications

Days in hospital

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 project, we will deliver the much-needed 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

To compare surgical strategies for vascular access creation in elderly hemodialysis patients.

Study design

Parallel group, multicenter randomized controlled trial.

Intervention

Subjects will be randomized into three study groups with a different surgical

strategy for the creation of a vascular access for hemodialysis:
1. Autologous arteriovenous fistula creation (recommended by current guidelines)
2. Arteriovenous graft implantation
3. Central venous catheter placement

Study burden and risks

Burden: filling out the questionnaires will take 5 hours and can be done with the aid of nurses during dialysis treatments.

Risks:
There are three types of vascular access for hemodialysis: autologous arteriovenous fistulas, arteriovenous grafts, and central venous catheters. Each type of vascular access has its own advantages and disadvantages. Autologous arteriovenous fistulas have the least long-term complications, but maturation into a functional access takes time and often does not succeed. Arteriovenous grafts can be used early but more often experience stenosis and thrombosis. Central venous catheters can be used immediately and are placed with a minimally invasive procedure, but are associated with increased risk of serious infections and mortality in observational studies. Participation in this trial exposes the subject to the risks (as well as the benefits) of the allocated type of vascular access.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyeplein 25
Maastricht 6202AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyeplein 25
Maastricht 6202AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. Adult patients aged 65 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 disease
4. Fit for vascular access surgery as determined by the local multidisciplinary vascular access team
5a. Expected to start hemodialysis treatment within 6 months at the time of treatment assignment; or
5b. 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 usually 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-12-2019
Enrollment:	195
Type:	Actual

Medical products/devices used

Generic name:	Vascular graft;central venous dialysis catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-04-2020
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-05-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-08-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-10-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-03-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-10-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	15-05-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-07-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2024
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

ID: 28751
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70385.068.19