Dutch nOcturnal and hoME dialysis Study To Improve Clinical Outcomes: the prospective study.

Published: 07-12-2017
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To analyse the effects of home dialysis - both peritoneal dialysis (PD) and (nocturnal) home haemodialysis - on quality of life, clinical outcomes (anaemia control, hospitalisation, mortality etc.) and total costs compared with in-centre...

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

Summary

ID

NL-OMON52673

Source
ToetsingOnline

Brief title
DOMESTICO - prospective

Condition

- Renal disorders (excl nephropathies)

Synonym
Chronic Kidney Disease, End Stage Renal Disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC - Locatie AMC en VUmc
Source(s) of monetary or material Support: ZonMW,Baxter,Fresenius Medical Care,Fresenius;Baxter

Intervention

Keyword: Cost-effectiveness, Home haemodialysis, Peritoneal dialysis, Quality of life

Outcome measures

Primary outcome

- To compare quality of life between patients on home dialysis - both PD and home (nocturnal) HD - and patients treated with conventional in-centre HD.

Secondary outcome

- To compare standard clinical outcome parameters (blood pressure, haemoglobin and phosphate control, protein energy wasting) in home dialysis patients, with those in a comparison group of patients treated with conventional in-centre HD;
- To analyse the incidence and causes of technique failure of home dialysis - both PD and home (nocturnal) HD;
- To compare infectious and non-infectious hospitalisation (rate, time to first hospitalisation and length of hospital stay) between patients on home dialysis and patients treated with conventional in-centre HD;
- To compare the mortality rate between patients on home dialysis and patients treated with conventional in centre-HD;
- To compare total costs in home dialysis compared to conventional in-centre HD, in order to determine cost-effectiveness of home dialysis;
- To analyse experiences of caregivers and caregiver burden.

Study description

Background summary

The percentage of patients treated with a form of home dialysis (peritoneal dialysis and home haemodialysis combined) is steadily decreasing over the past 15 years in the Netherlands, from 33% in 2002 to 18% in 2017. Also, there is remarkable practice variation in the percentage of home-dialysis-treated patients in Dutch dialysis centres. Both past performance and practice variation indicate an underuse of home-based dialysis. Patients treated at home might obtain greater freedom from managing their own treatment, presuming positive effects on quality of life. On the other hand, the dialysis population has changed during the last decade. Young patients often undergo pre-emptive kidney transplantation, thus the dialysis population consists of older patients with more comorbidities.
This study is designed to study long-term effects of home dialysis in the current dialysis population.

Study objective

To analyse the effects of home dialysis - both peritoneal dialysis (PD) and (nocturnal) home haemodialysis - on quality of life, clinical outcomes (anaemia control, hospitalisation, mortality etc.) and total costs compared with in-centre haemodialysis (HD). In addition, the course of caregiver experience will be assessed.

Study design

A prospective multicentre observational cohort study of all incident patients that start either peritoneal dialysis or (nocturnal) home haemodialysis between 20-12-2017 and 31-12-2022, with registration of quality of life. In addition clinical outcomes (blood pressure control, mortality etc.) and total costs, will be included as secondary endpoints in comparison to a group of patients that start conventional in-centre HD. In addition, caregivers of patients will be included to asses caregiver experience for home and in-centre hemodialysis. The intended follow-up is 12-72 months with expected end of the study on 31-12-2023.

Study burden and risks

There is no burden or risk associated with participation to this study due to design if this study (observational).

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

Patient
- Age > 18 years
- Indication to start with RRT
- Willingness to start with a form of RRT

Caregiver
- The subject must care for a partner, family member, friend or a loved one with end-stage kidney disease that is treated by dialysis therapy and is included into the DOMESTICO study
- The subject must be 18 years and older

Exclusion criteria

Patient
- unwillingness to provide informed consent
- life expectancy < 3 months
- expected renal transplantation < 3 months

- unable to fill in questionnaires (including active cognitive disease, active psychiatric disorder or language barrier other than the languages provided)

Caregiver
- Caregivers who do not provide informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2017
Enrollment:	2084
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 23350
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63277.029.17
OMON	NL-OMON23350