

Dutch nOcturnal and hoME dialysis Study To Improve Clinical Outcomes

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Home dialysis results in improvement of quality of life, at least comparable clinical outcomes and lower costs, compared to in-centre HD.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23350

Bron

Nationaal Trial Register

Verkorte titel

DOMESTICopro

Aandoening

CKD, Home Dialysis, Peritoneal Dialysis, Home Haemodialysis, PROMs, Quality of Life, Cost-effectiveness, ESRD, Renal Replacement Therapy.

nierfalen, chronische nierschade, thuisdialyse, peritoneale dialyse, thuishaemodialyse, kwaliteit van leven, kosteneffectiviteit, nierfunctie vervangende therapie.

Ondersteuning

Primaire sponsor: VU University Medical Center Amsterdam (VUmc)
 University Medical Center Utrecht (UMCU)

Overige ondersteuning: ZonMw
 Baxter
 Fresenius

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life, obtained from the following questionnaires: SF-12, Dialysis Symptom Index and EQ5D-5L

Toelichting onderzoek

Achtergrond van het onderzoek

End-stage renal disease (ESRD) is a common and costly health care problem affecting all age groups.

Although the absolute number of patients treated with dialysis in The Netherlands is low (6500 dialysis patients in 2016), it is by far the largest cost-consumer of all treatment modalities in general.

Most dialysis patients are treated 3 times a week during 4 hours with haemodialysis at a dialysis centre (conventional in-centre HD). However, dialysis can also be performed at home, in the form of peritoneal dialysis (PD) or home HD. Dialysis treatment at home is considered to be at least equally effective regarding survival. However, the percentage of patients treated with a form of home dialysis (either PD or home HD) has steadily decreased over the past 15 years in The Netherlands, from 33% in 2002 to 18% in 2016 (www.nefrodata.nl). This decline is mainly attributable to a reduction in the number of PD patients, due to pre-emptive transplantation.

Starting dialysis has major impact on QoL of patients. However, recent available evidence regarding the effects of home dialysis on QoL compared with in-centre HD is limited and outdated. The studies are small and all have a cross-sectional design. Furthermore, patients starting with a form of home dialysis have changed remarkably over the past years: home dialysis patients used to be young, employed and with little comorbidities, whereas during the last years the general home dialysis population is older and suffers from cardiovascular disease. Therefore, an update of older data on clinical outcomes of home dialysis in relation to in-centre HD is necessary.

Doel van het onderzoek

Home dialysis results in improvement of quality of life, at least comparable clinical outcomes

and lower costs, compared to in-centre HD.

Onderzoeksopzet

baseline, 3 months, 6 months, and every 6 months thereafter until end of follow-up or end of study.

Onderzoeksproduct en/of interventie

Home dialysis, both peritoneal dialysis and home haemodialysis

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 years

- indication to start with RRT
- willingness to start with a form of RRT

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-12-2017
Aantal proefpersonen:	1600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	22-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52673

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6519
NTR-old	NTR6736
CCMO	NL63277.029.17
OMON	NL-OMON52673

Resultaten