

# Dutch nOcturnal and hoME dialysis Study To Improve Clinical Outcomes

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON23350

### Source

NTR

### Brief title

DOMESTICopro

### Health condition

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, nierfunctievervangende therapie.

## Sponsors and support

**Primary sponsor:** VU University Medical Center Amsterdam (VUmc)<br>University Medical Center Utrecht (UMCU)

**Source(s) of monetary or material Support:** ZonMw<br>Baxter<br>Fresenius

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

clinical outcomes (phosphate and anaemia control, nutritional status, infectious complications, hospitalisation, mortality) and cost-effectiveness.

## Study description

### Background summary

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](http://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recent available evidence regarding the effects of home dialysis on QoL compared with in-centre HD is limited and outdated.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.

## Study objective

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

## Study design

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

## Intervention

Home dialysis, both peritoneal dialysis and home haemodialysis

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

- Age > 18 years
- indication to start with RRT

- willingness to start with a form of RRT

## Exclusion criteria

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

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	20-12-2017
Enrollment:	1600
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	22-08-2017
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 52673

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

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

## Study results