# Uremic Toxins, Cardiovascular Effects and Physical Activity in Intensive Hemodialysis

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Urinary tract signs and symptoms |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON39123

**Source**
ToetsingOnline

**Brief title**
Long-term Effects of Intensive Hemodialysis

### Condition

- Urinary tract signs and symptoms

**Synonym**
end-stage renal disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W,Fresenius MC en Baxter

## Intervention

**Keyword:** intensive hemodialysis, nocturnal hemodialysis, pulse wave velocity, uremic toxins

## Outcome measures

### Primary outcome

-Pulse wave velocity

### Secondary outcome

-Levels of uremic toxins

-Physical activity

# Study description

### Background summary

End-stage renal disease (ESRD) patients on dialysis have high annual mortality rates. Kidney transplantation is the gold standard renal replacement therapy. However, the demand for kidney transplantation exceeds the supply of organs. Intensive hemodialysis is associated with significant improvement of biochemical, biological and clinical parameters. This may be due to increased clearance of uremic toxins and optimized volume control leading to improved vascular biology and reduced cardiovascular disease. Furthermore, intensive hemodialysis patients may have better physical activity scores and quality of life which may further reduce morbidity and mortality in these patients.

### Study objective

The primary objective of this study is to compare vascular biology (vascular markers and endothelial microparticles) and cardiovascular effects (volume status, blood pressure, pulse wave velocity and microcirculation) in conventional hemodialysis (CHD), intensive HD [Short Daily Hemodialysis (SDHD), nocturnal hemodialysis (NHD) (3 nights per week) and home NHD (HNHD) (5 to 6 nights per week)] and peritoneal dialysis (PD) patients. The secondary objectives of this study are to compare the kinetics and levels of uremic toxins as well as the degree of physical activity in patients treated with these different dialysis modalities.

### Study design

Incident and prevalent CHD, intensive HD [SDHD, NHD and HNHD] and peritoneal dialysis (PD) patients will be prospectively followed up in an observational study over a period of 2 years. All patients will be included in the study over a period of 2 years. Every 6 months, vascular parameters will be meausred in blood samples. Also, body composition (with BCM), pulse wave velocity (with Sphygmocor), echocardiography (evaluation of left ventricular hypertrophy and fluid status), microcirculation (with capillaroscopy), 24-hour blood pressure (with Mobil-O-Graph) and physical activity (with Sensewear) will be measured. Also, patients will be requested to fill out a quality of life questionnaire at the time of each visit. Last, predialytic and postdialytic levels of several uremic toxins will be measured during a mid-week dialysis session.

### Study burden and risks

In this study, only non-invasive techniques which pose a minimal burden to the patient will be used. Blood sampling will coincide with the dialysis sessions. The study will not have direct benefit for the participants. The study can only be performed with this specific patient group.

## 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

-Incident and prevalent conventional hemodialysis (CHD), intensive HD [short daily hemodialysis (SDHD), nocturnal hemodialysis (NHD) and home nocturnal hemodialysis (HNHD)] and peritoneal dialysis (PD) patients
-Different patient groups (CHD, intensive HD and PD) will be matched according to transplantation candidature en Charlson Comorbidity Index
-Standard renal diet (80 g of protein per day)
-Age > 18 years
-Informed consent

## Exclusion criteria

-Charlson risk index of 5 or higher
-Chronic antibiotic use and colectomy because of interference with uremic toxin formation and degradation
-Withdrawal of consent
-For bio-impedance measurements: presence of ICD or pacemaker. There are no restrictions for other measurements in these patients.

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 31-08-2012 |
| Enrollment: | 140 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 27-04-2011 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 02-01-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 01-08-2013 |
| 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

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL35039.068.10 |