Physical performance and protein energy wasting in patients starting with nocturnal hemodialysis compared to conventional hemodialysis: the DiapriFit study

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The aim of this trial is to study if physical performance improves and protein energy wasting decreases in patients who change from conventional hemodialysis to nocturnal hemodialysis, compared to patients who continue their treatment on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON45059

Source
ToetsingOnline

Brief title
DiapriFit study

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Nephropathies

Synonym
malnutrition, nocturnal hemodialysis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Baxter Global,Baxter Global; er wordt nog subsidie aangevraagd bij Sanofi/Genzyme en bij Nutricia;bij WBSO

Intervention

Keyword: nocturnal hemodialysis, physical performance, protein energy wasting

Outcome measures

Primary outcome

Primary objective:

Does the change from conventional hemodialysis to nocturnal hemodialysis lead to

improved physical performance?

Secondary outcome

Secondary objective:

Does the change from conventional hemodialysis to nocturnal hemodialysis lead to

decreased protein energy wasting?

Study description

Background summary

Cardiovascular disease (CVD) is the leading cause of death in patients with end-stage renal disease (ESRD) (Parfrey 1999). This increased mortality is attributed to several factors. First, the major hemodynamic impact of extracellular fluid overload, alternating with periods of dehydration and hypotension, lead to dilating cardiomyopathy en left ventricular dysfunction. Second, the continuous hyperphosphataemia as a direct result from diminished glomerular filtration, often in combination with hypercalcaemia and hyperparathyroidism, cause gross calcifications in larger blood vessels. These are strongly associated with the occurrence of cardiovascular events. Third, protein energy wasting defined as diminished food intake, protein catabolism, increased energy expenditure, inflammation and fluid retention, contributes to mortality by increasing cardiovascular and infectious complications.

Nocturnal hemodialysis is characterized by a twice as long and somewhat less intense hemodialysis treatment. Frequent nocturnal hemodialysis, i.e. 5-6x/week, has been shown to improve volume control, to diminish left ventricular hypertrophy, and to stabilize blood pressure compared to conventional hemodialysis (Culleton 2007, Freq HD Network 2011, Ok 2011). It also provides more intense clearance of solutes, especially of urea and phosphate. Observational data also show an increase in body weight in patients treated with nocturnal hemodialysis (Sikkes 2009, Ok 2011). However, other aspects of protein energy wasting, such as subjective global assessment, body composition and mid-arm muscle circumference are not yet investigated. Some data are available on physical aspects of quality-of-life, showing no difference between conventional versus nocturnal hemodialysis (Rocco 2011; Schorr 2011, Hall 2012). Furthermore, functional outcomes of protein energy wasting, such as physical performance, gait speed en muscle strength have remained underexposed.

Study objective

The aim of this trial is to study if physical performance improves and protein energy wasting decreases in patients who change from conventional hemodialysis to nocturnal hemodialysis, compared to patients who continue their treatment on conventional hemodialysis.

Study design

The study design is a controlled intervention study, which compares starting nocturnal hemodialysis with continuing conventional hemodialysis . Thus, two groups of patients will be included:
A. Intervention group: 25-35 patients that have been treated with conventional hemodialysis (2-3 x/wk, 3-5 h), who start with in-center nocturnal hemodialysis (3-4 x/wk, 7-9 h), i.e. incident nocturnal hemodialysis patients;
B. Control group: 25-35 patients that have been treated with conventional hemodialysis (2-3 x/wk, 3-5 hr), who want to continue their treatment with conventional hemodialysis/hemodiafiltration in the same way.
As it is not possible to randomize patients for nocturnal vs. conventional hemodialysis, the groups are matched as much as possible regarding criteria that determine the primary outcome parameter (physical performance). We therefore recruit every incident nocturnal hemodialysis patient if he/she has given informed consent, and recruit a control patient on conventional hemodialysis/hemodiafiltration from another dialysis center after matching for age (± 5 years), body mass index (± 3 kg/m2), dialysis vintage (< 5 or > 5 yr) and transplantability (yes/no).
Physical performance and protein energy wasting will be assessed at time points: t = -2 months, 0 months, and 3, 6 and 12 months follow-up; where t = 0 is the switch from conventional dialysis to nocturnal dialysis for the intervention group. Two baseline measurements with a 2-month interval will be

assessed in order to adjust for possible *learning effect* during the assessment of the physical performance tests, and to improve objectiveness of the baseline measurement .

Study burden and risks

- there is no risk attributable to participation to this study
- the burden consists of time investment, of which part can be done during hemodialysis treatment

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

- hemodialysis or hemodiafiltration treatment of more than 3 months, with stable hemodialysis regarding weight, blood pressure, and no active infection.
- for the intervention group consent to switch from conventional hemodialysis 2-3 times/week 3-5 hours, to nocturnal hemodialysis 3-4 times/week 7-9 hours.
- ability to understand the study protocol.
- informed consent.
- age >= 18 years and <= 80 years of age.

Exclusion criteria

- dementia
- life expectancy < 12 months
- planned renal transplantation within 12 months
- instable angina pectoris
- recent myocardial infarction
- severe pulmonary disease
- treatment incompliance, i.e. non-adherence to dialysis regimen

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	22-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2017
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: 24999
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL44792.029.13
OMON	NL-OMON24999