The effect of more efficient hemodialysis on body composition measured by Dual Energy X-ray Absorptiometry (DEXA).

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With this pilot study we want to see if there are measurable differences in body composition after one year. In what way does the body composition of patients change during the first year after transition from CHD to NHHD or NCHD? Is the weight gain...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON31784

Source
ToetsingOnline

Brief title
Body composition and nocturnal hemodialysis

Condition

- Appetite and general nutritional disorders
- Renal disorders (excl nephropathies)

Synonym
hemodialysis, renal replacement therapy

Research involving
Human

Sponsors and support

Primary sponsor: Dialyse Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: body composition, DEXA, nocturnal hemodialysis

Outcome measures

Primary outcome

Body weight (kg)

Fat mass (g)

Lean body mass (g) existing of muscles, bone tissue and fluids

Secondary outcome

hemoglobin (mmol/l), serum albumin (g/), serum calcium (mmol/l) and phosphate

(mmol/l)

equilibrated Kt/V (eKt/V) and Protein Catabolic Rate (PCR, g protein/ kg /day)

Study description

Background summary

Hemodialysis patients have a high risk of malnutrition. The cause of malnutrition is multifactorial. Contributing factors are higher energy-needs, chronic fatigue, the dialysis process itself, and reduced food intake. Reduced food intake can have many causes like: less eating moments at dialysis days, nausea as a result of hemodialysis, dietary restrictions, xerostomia, and reduced taste perception.

Frequent nocturnal home hemodialysis (NHHD) is currently the most effective method of hemodialysis and is associated with low blood levels of uremic toxins. The patients dialyze 5 to 6 nights a week 8 hours during their sleep at home. The conventional hemodialysis (CHD) scheme is 3 times a week 3 to 5 hours dialysis. Patients on nocturnal in-centre hemodialysis (NCHD) dialyse on alternate nights (every other night) 8 hours during their sleep in the dialysis centre.

A research for changes in food intake at NHHD patients is currently going on in Dialysis Centre Groningen (DCG). The first results show a weight gain and an increase in energy intake after the transition from CHD to NHHD after 4 months,

after this first period it seems to stabilize. The same research is also started in patients who started with NCHD. It is still unknown if the weight gain is caused by an increase in fat, or an increase in lean body mass, or maybe in both.

A literature study showed that Dual Energy X-ray Absorpiometry (DEXA) is the best possible method to measure the body composition of dialysis patients. Several studies published that DEXA is a safe, fast, and accurate measurement. The measurement has a low burden for the patient, which makes this a suitable measurement for dialysis patients.

Study objective

With this pilot study we want to see if there are measurable differences in body composition after one year.
In what way does the body composition of patients change during the first year after transition from CHD to NHHD or NCHD? Is the weight gain a result of an increase in fat or in lean body mass? The body composition will be measured by DEXA, Whole Body Composition (WBC).

Study design

A DEXA (WBC) scan will be done before the transition from CHD to NCHD/NHHD, baseline, and after one year NCHD/NHHD the same measurement will be repeated.

Study burden and risks

The research is combined with a bone density measurement (bdm), which is a standard measurement for these patients before start NHHD/NCHD and after 1 year. In total patients will have to spend 2 times 25 minutes with one year interval.
Two times WBC and bdm DEXA will deliver a radiation burden of 0.316 mSv for the research group. This is including the 0.30 mSv radiation burden of two times the bdm.
For the control group the 2 WBC DEXA measurements will deliver a total radiation burden of 0.016 mSv in one year.

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

frequent home and in-centre nocturnal hemodialysis patients (age 18 years or older)

Exclusion criteria

short life expectance (<1 year), a substantial amount of metal in the body (artificial hip, pacemaker, and other), absence of informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL19284.042.07