The influence of superflux dialysis on the uremic toxicity profile: a comparison with post-dilution hemodiafiltration and low flux hemodialysis

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON31344

Source
ToetsingOnline

Brief title
superflux dialysis and uremic toxins

Condition

- Nephropathies

Synonym
end stage renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Nipro Corporation; Osaka; Japan. NB: het betreft een investigator-driven studie.

Intervention

Keyword: hemodiafiltration, hemodialysis, superflux, uremic toxins

Outcome measures

Primary outcome

The primary outcome parameter is the pre-dialytic plasma level of Beta-2 microglobulin.

Secondary outcome

Plasma levels and clearance of other larger molecular weight toxins (such as complement factor D, carboxmethyllysine, homocysteine). Albumin loss during treatment and the effect on immune status [FACS] will also be studied.

Study description

Background summary

Hemodialysis with so-called low flux membranes is the most commonly used dialysis technique. On-line hemodiafiltration is increasingly used as an alternative treatment, because with this technique also larger uremic toxins can be removed. On-line hemodiafiltration is however a more complicated technique from a technical point of view, and can only be performed with specialized dialysis modules which are not available in all dialysis centres.
With the use of very permeable (so-called superflux) membranes it might be possible to achieve a comparable clearance of larger uremic toxins compared to on-line hemodiafiltration. However, this has not yet been studied.
The hypothesis of the present study is that hemodialysis with superflux membranes, and on-line hemodiafiltration are equivalent with regard to the clearance of larger uremic toxins and will have similar effects on plasma levels of these toxins, and are superior to low-flux hemodialysis in this respect.

Study objective

Aim of the present study is to compare the effects of low-flux hemodialysis, post-dilution on-line hemodiafiltration, and superflux dialysis with regard to clearance and pre-dialytic levels of larger uremic substances. Moreover, the effects of these techniques on albumin losses and immune status will be studied.

Study design

In this single-centre study, treatments will be compared in a randomised cross-over design. Twenty patients will be included. After a run-in period of 1 months in which all patients are continued to be treated with low-flux hemodialysis, patients will either be randomised to treatment with superflux dialysis for a period of 8 weeks, followed by 8 weeks treatment with post-dilution on-line hemodiafiltration (A-B), or to treatment with post-dilution on-line hemodiafiltration, followed by superflux dialysis (B-A).

Study burden and risks

Hemodialysis and on-line hemodiafiltration are accepted treatments. The time burden for the pateint is minimal, all measurements are performed during the dialysis treatment. The estimated albumin loss during superflux dialysis and on-line hemodialfiltration is estimated to be comparable to peritoneal dialysis (a regular dialysis technique by which approximately 30% of the total dialysis population is treated) Plasma albumin levels will be closely followed.
Regarding blood sampling, it is not to be expected that the withdrawal of 180 ml of blood during a period of 5 months will have negative effects on the hemoglobin level of the patient. As with every dialysis membrane, there is a small risk for allergic reactions with the use of cellulose triacetate membranes. This risk is however not increased compared with other dialysis membranes.
There are no expected benefits for the patient. Regarding group relatedness, this study can only be performed by the specific group of patients.

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

Patients treated with chronic low-flux hemodialysis (longer than 3 months)
Older than 18 years
Ability to give informed consent

Exclusion criteria

Acute renal failure
Inability to give informed consent
Prior treatment with on-line hemodiafiltration within the last 6 months
Severe intercurrent disease
Dementia
Life expectancy less than 6 months
history of hypersensitivity reaction to polysulphone or cellulose triacetate

Study design

Design

Study type: Observational invasive

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	hemodialyzer
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-06-2007
Application type:	First submission
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	NL17108.068.07