The intradialytic clearance of polyclonal immunoglobulin free light chains by low-flux hemodialysis, high-flux hemodialysis and online hemodiafiltration .

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Study the clearance of immunoglobulin free light chains by HDF, lf-HD and high flux hemodialysis (hf-HD) using polysulphone and polyamide dialyzers.

Ethical review	Approved WMO
Status	Pending
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35927

Source
ToetsingOnline

Brief title
Clearance of Ig free light chains by different dialysis modalities.

Condition

- Immune disorders NEC
- Bacterial infectious disorders
- Renal disorders (excl nephropathies)

Synonym
End stage renal disease, infections

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Afdelingsgeld voor onderzoek gereserveerd

Intervention

Keyword: Dialyzer, Free light chains, Hemodiafiltration, Hemodialysis

Outcome measures

Primary outcome

The difference in change of immunoglobulin free light chain serum concentration

during the hemodialysis session.

Secondary outcome

N.a.

Study description

Background summary

In an earlier study we found that immunoglobulin free light chains were better removed by online hemodiafiltration (HDF) than by low-flux hemodialysis(lf-HD), it appears that this difference in clearance might be caused by different membrane materials instead of by the difference in dialysis modality.

Study objective

Study the clearance of immunoglobulin free light chains by HDF, lf-HD and high flux hemodialysis (hf-HD) using polysulphone and polyamide dialyzers.

Study design

Randomised cross-over study

Intervention

During six consecutive weeks all patients will undergo a midweek hemodialysis session with each combination of dialysis modality and dialyzer (all common therapies). Before and after this dialysis session blood samples will be taken

from the lines of the dialysis machine. At two timepoints (lf-HD en HDF with polysulphone dialyzers) some extra blood will be taken for extra measurements.

Study burden and risks

All study procedures will take place during patients habitual dialysis visits. Patients that will be included in this study normally undergo lf-HD with polysulphone membranes. At the midweek dialysis days of 6 consecutive weeks, they will be switched to the other modalities and dialyzers for one treatment session. Al these modalities and dialyzers are being used in daily clinical practice. We will take blood samples (2 tubes) on 6 days, before and after the dialysis session. Before and after the lf-HD and HDF session with polysulphone we will take 2 tubes extra blood for storage for other measurements. Patients do not have to undergo venapunctures, since the blood will be taken from the dialysis lines.

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

Prevalent hemodialysis patients, treated with hemodialysis 3 times a week (for at least 2 months) with a minimum dialysis urea Kt/V >= 1.2 and who are able to understand the study procedures.

Exclusion criteria

Exclusion criteria are age < 18 years, treatment by hemodiafiltration or high-flux hemodialysis in the 6 months preceding entering this study, severe incompliance defined as non-adherence to the dialysis prescription and a life expectancy < 3 months due to causes other than kidney disease. Hemoglobin level < 6.0 mmol/L.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-06-2011
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-07-2011

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL36474.101.11