Comparison of dialysate- and plasma clearences between three different haemodialysis modes.

Published: 20-05-2008
Last updated: 08-05-2024

Primary research question: Is there a difference in plasma- and dialysate clearances of middle molecules and larger molecules, with different electrical charges, between treatment with standard haemodialysis, high-flux haemodialysis and on-line...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON31119

Source
ToetsingOnline

Brief title
Comparison of clearence between different haemodialysis modes.

Condition

- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
haemodialysis, treatment with artificial kidney

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: FBW Nierziekten. ,Gambro b.v.

Intervention

Keyword: Hemodiafiltration, High flux hemodialysis, Low flux hemodialysis, Solute clearence

Outcome measures

Primary outcome

Dialysate samples: Samples collected: continuously and separated in aliquots

every hour.

Phosphate, Cystatine C, Beta 2 Microglobuline, Vitamin B12, Urea, Creatinin.

Blood samples:

Before start treatment: Haemoglobin, Haematocrit, Albumin, CRP.

Before and during treatment: Samples collected: before treatment, every hour

and at treatment end.

Before artificial kidney and just before venous return. (i.e. after post

dilution substitution)

Phosphate, Cystatine C, Beta 2 Microglobuline, Vitamin B12, Urea, Creatinin,

Albumin, Haematocrit.

Once every type of treatment: D-dimeer en TAT as measures of degree of clotting

in the artificial kidney. Before and after treatment.

Anti- Xa as measure of activity of Nadoparin. Before and after treatment.

C3D as measure of complement activation. After treatment.

Secondary outcome

- Diascan measurement on the Gambro AK 200-Ultra S.

Study description

Background summary

In patients with end-stage renal disease (ESRD) treated with standard low-flux haemodialysis, many solutes still accumulate. This accumulation probably is responsible for several long-term complications of chronic haemodialysis.
On-line haemodiafiltration combines diffusive- and convective clearance and is considered to be superior in clearance of middle- and larger molecules. Several studies have examined the difference between haemodialysis and on-line haemodiafiltration regarding long-term morbidity and mortality. None of these studies has examined in detail the plasma clearance and dialysate clearance of middle- and large molecules.

In this study we will examine the plasma- and dialysate clearances of phosphate, several middle molecules (500 - 5000 Dalton) and larger molecules. Phosphate is a small molecule (96 Dalton) but its clearance appears to be very different from the clearance of other small molecules.

Study objective

Primary research question:
Is there a difference in plasma- and dialysate clearances of middle molecules and larger molecules, with different electrical charges, between treatment with standard haemodialysis, high-flux haemodialysis and on-line haemodiafiltration?

Secondary research question:
Is the dialysis Kt/V measured with Diascan comparable to the single pool (DaugirdasII) Kt/V and/or the equilibrated Kt/V calculated with BUN measurements in blood samples before, during and after dialysis

Study design

Study design:
Clinical-, prospective-, randomised-, crossover study.

Intervention

Treatment 1: Low-flux haemodialysis
Qb: 350ml/min
Qd: 700ml/min. Temp: 36°C
Gambro AK 200 Ultra S
Gambro Polyflux 17 L
4 hours
Nadoparin: 1st shot and 2nd shot after 2 hours.

Treatment 2:
High-flux haemodialysis
Qb: 350ml/min
Qd: 700ml/min. Temp: 36°C
Gambro AK 200 Ultra S
Gambro Polyflux 170H
4 hours
Nadoparin: 1st shot and 2nd shot after 2 hours.

Treatment 3:
On-line haemodiafiltration Postdilution.
Qb: 350ml/min
Qd: 700ml/min. Temp: 36°C
Qs: 25% of Qb minus UF
Gambro AK 200 Ultra S
Gambro Polyflux 170H
4 hours
Nadoparin: 1st shot and 2nd shot after 2 hours.

Study burden and risks

Nature and extent of the burden and risks are considered minimal.

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

Dialysis patients > 18 years of age.
Dialysis > 3 months.
Signed informed consent.
Uncomplicated hemodialysis.
AV fistula with flow > 350ml/min.
Residual function < 1 ml/min.
Hemoglobin level between 6.8 - 8.3 mmol/l.
No bleeding tendency.

Exclusion criteria

Instable dialysis
No bleeding tendency.
No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Different dialysis modes
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL18545.091.07