Is the lower incidence of intradialytic hypotension during Hemocontrol dialysis in comparison with standard hemodialysis attributable to enhanced to higher plasma vasopressin levels or to enhanced sympathetic activity and/or to less nitric oxide production?

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Objectives1. To investigate whether the improved hemodynamic stability with Hemocontrol dialysis is based on higher plasma levels of vasopressin or on enhanced activity of the sympathetic nervous system and/or inhibition of nitric oxide production....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37739

Source
ToetsingOnline

Brief title
Vasopressin, sympathetic activity, nitric oxide, dialysis hypotension

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym

Dialysis hypotension

Health condition

Vasopressine, sympathicusactiviteit, stikstofoxideproductie en dialyse hypotensie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dialysis hypotension, Hemocontrol, sympathetic activity, vasopressin

Outcome measures

Primary outcome

Primary outcome

Plasma vasopressin levels

Secondary outcome

Secondary outcomes

Sympathetic activity (primarily defined as the low frequency band in measurements of heart rate variability, secondarily defined as plasma noradrenalin levels) and nitric oxide metabolites as a parameter of endogenous nitric oxide production of vascular endothelial cells. In addition, plasma sodium levels, plasma osmolality, baroreflex sensitivity, peripheral vascular resistance and the course of the relative blood volume, blood pressure and heart rate.

Study description

Background summary

Background
Rationale:
Intradialytic hypotension (IDH) is a frequent and serious complication that may occur during hemodialysis treatment. We and others have shown that the Hemocontrol biofeedback system is associated with improved hemodynamic stability. Hemocontrol is a technique that guides the patients* blood volume along a pre-set trajectory by continuously adjusting the ultrafiltration rate and dialysate conductivity. In a recent pilotstudy (Vasopressinestudie, ABR-nr 29707 + NDT ref DOI#) we found significantly higher plasma vasopressin levels during the first hour of dialysis with Hemocontrol in comparison with standard hemodialysis. Increased vasopressin levels may contribute to intra-dialytic hemodynamic stability during HD by enhanced vasoconstriction.
These results, however, did not prove directly that the improved hemodynamic stability with Hemocontrol is indeed caused by higher initial plasma vasopressin levels.
Alternative explanations might be that 1) the higher initial plasma sodium levels with Hemocontrol dialysis enhance activity of the sympathetic nervous system directly, causing vasoconstriction and thereby improved hemodynamic stability and/or 2) that the higher initial plasma levels of sodium in Hemocontrol inhibit the release of nitric oxide by the vascular endothelium.
In this study, we also want to investigate whether vasopressin is removed with hemodialysis.

Study objective

Objectives
1. To investigate whether the improved hemodynamic stability with Hemocontrol dialysis is based on higher plasma levels of vasopressin or on enhanced activity of the sympathetic nervous system and/or inhibition of nitric oxide production.
2. To investigate whether vasopressin is removed by hemodialysis

Study design

Study design
In a randomized cross-over design, 30 hemodialysis patients who are on a thrice weekly hemodialysis schedule, shall be treated once with standard hemodialysis and once with Hemocontrol hemodialysis.
Non-invasive measurements performed are:
- Before, after 30, 60, 120 and 180 minutes and after dialysis blood is withdrawn from the dialysis line to determine plasma levels of vasopressin,

sodium, noradrenalin, nitric oxide metabolites and plasma osmolality.
In addition, blood will also be drawn from all patients on Hemocontrol hemodialysis when it has passed the artificial kidney at 30 minutes on dialysis. In total, 168 ml of blood (84 ml per dialysis session) will be drawn.
- Measurement of blood pressure, heart rate, peripheral vascular resistance, heart rate variability, baroreflex sensitivity and cardiac output with the Finapress. This is a non-invasive measurement using a fingercuff.
- Relative blood volume changes are measured with an incorporated non-invasive continuous hemotocrit meter.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients who are normally treated with standard hemodialysis shall undergo one hemodialysis with Hemocontrol and patients who are normally treated with Hemocontrol hemodialysis shall undergo one standard hemodialysis. Both treatments are routinely and qualitatively comparable treatments. A total of 168 ml of blood (84 ml per dialysis treatment) shall be withdrawn from the dialysis line, so patients do not have to undergo extra venipunctures.
Patients will be asked to wear the vingercuff of the Finapress for ten minutes every half hour. Patients will also be asked not to smoke or to consume caffeine containing products like coffee, tea and chocolate from 10 o*clock pm the night prior to the dialysis.
It is possible that patients undergo hemodialysis at a different point of time than usual.
There are no risks associated with participating in this study. We believe that the limited burden of this study is justifiable since we expect that the study shall provide relevant knowledge about the pathofysiology of intradialytic hypotension and might contribute to new options in the treatment of this frequent complication occurring during hemodialysis.

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

Hypotension-prone dialysis patients including patients who have stable hemodialysis session on Hemocontrol but previously had dialysis hypotension on standard hemodialysis

Exclusion criteria

Patients on hemodialysis duration < 4 hours or > 4 hours

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2012
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	NL39186.042.12

Study results

Date completed:	25-03-2013
Actual enrolment:	30