Can the beneficial effect of Hemocontrol on blood pressure during dialysis be explained by higher blood levels of vasopressin. A pilot study.

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Based on the hypothesis that hemodialysis with Hemocontol is associated with a greater and earlier increase in plasma vasopressin levels than standard dialysis, we examine whether there is a difference in the course of plasma vasopressin levels...

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

Summary

ID

NL-OMON35305

Source
ToetsingOnline

Brief title
The influence of Hemocontrol hemodialysis on vasopressin levels

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
dialysis hypotension

Health condition

invloed van hemodialyse op afgifte van het hormoon vasopressine

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hemocontrol, hemodialysis, vasopressin

Outcome measures

Primary outcome

The course of plasma vasopressin levels, sodium, urea, glucose and plasma

osmolarity.

Secondary outcome

Registration of blood volume, blood pressure and heart rate.

All research-dialyses during the 1st dialysis of the week

Registration of the attitude of the patient during hemodialysis and what the

patient eats and drinks during hemodialysis.

Study description

Background summary

Introduction and reason for a study of vasopressin in hemodialysis:
Recently described van der Zee et. al that the plasma vasopressin levels during hemodialysis hardly increased despite the occurrence of hypovolemia due to ultrafiltration. They also found in a randomized placebo-controlled trial that exogenously administered vasopressin during hemodialysis kept the blood pressure on a higher level than the placebo.
They found that end-stage renal disease (ESRD) had no influence on the 'endogenous removal rate' of plasma vasopressin and vasopressin was not removed during dialysis. Vasopressin also has a molecular weight> 1000 Da and is not bound to protein.

In another study with 5 patients the vasopressin levels increased also significant, but the increase was very modest and significantly less than healthy individuals show a similar decrease blood volume.

Hemocontrol dialysis is a technique which leads the relative blood volume change along a preset desired path through continuous adjustment of the ultrafiltration rate and conductivity of the dialysate. An elevated dialysate conductivity leads (with some delay) to an increase in plasma sodium levels. This leads in principle to increase refill through osmosis of fluid from the interstitial tissue into the bloodstream. The boundaries of the dialysate conductivity are adjustable - the usual setting is a minimum and maximum conductance of 135 mmol / l and 160 mmol / l. In practice there is in the 1st half of the hemodialysis a combination of a high ultrafiltration rate and a high dialysate conductivity. In the 2nd half of the hemodialysis both the ultrafiltration rate and dialysate conductivity is lower. Low dialysate conductiveit in the 2nd half of the dialysis is necessary because the dialysis patient would otherwise end on a high plasma sodium concentration.

Hemocontrol gives stable dialysis as shown by us and others in hypotension-prone dialysis patients. It is assumed that the effect of Hemocontrol is based on a better maintaining (relative) blood volume. However, we and others found that the finally reached level of relative blood volume change was not significantly different between - unstable - the standard dialysis and the - stable - Hemocontrol dialysis. This does not exclude that a beneficial effect on blood volume Hemocontrol plays a role, for example through the prevention of sudden short-term decreases in the blood volume. Other factors may also play a role. In the past some researchers suggested that dialysis with a higher sodium dialysate has beneficial effects independent of effects on the blood volume. Thus it is possible that (a part of) the beneficial effects of vasopressin release during Hemocontrol dialysis are based on dialysis due to the higher plasma sodium conductance during the 1st half of the dialysis. In contrast with standard hemodialysis (with constant dialysate conductivity and ultrafiltration rate) provides dialysis Hemocontrol a 'double stimulus for vasopressin release, at least in the 1st half of the dialysis, the hypovolemia (which is during the 1st hours of dialysis is more pronounced than standard dialysis) and the higher plasma conductivity during the 1st half of dialysis compared with standard dialysis.
Would this study (and further research) find that vasopressin plays an important role, then this knowledge can be used to prevent hypotension during dialysis.

Study objective

Based on the hypothesis that hemodialysis with Hemocontol is associated with a greater and earlier increase in plasma vasopressin levels than standard dialysis, we examine whether there is a difference in the course of plasma

vasopressin levels between one standard and one HD and one HD Hemocontrol

Study design

Twelve patients will be part of this study, undergoing each 2 hemodialysis treatment , one with a standard hemodialysis (HD) and one with HD Hemocontrol, a crossover design in randomised order. During both HD treatments we will repeatedly take blood from the dialysis blood line for the determination of vasopressin, sodium, urea, glucose and plasma osmolarity. In total 66 cc.

Study burden and risks

Patients whom are normally treated with standard hemodialysis now get a single Hemocontrol hemodialysis and vice versa

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
• Patients in whom frequently more than 3 liter fluid has to be ultrafiltered during hemodialysis.

Exclusion criteria

• Patients on hemodialysis duration < 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):	20-09-2010
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2010
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	NL29707.042.10