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Clinical evaluation of Hemocontrol in hypotension-prone hemodialysis patients

Submission date	Recruitment status	[_] Prospectively registered
07/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/10/2017	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Hemodialysis (HD) is a process of purifying the blood of a person whose kidneys are not working normally. HD treatments may be complicated by a substantial drop in blood pressure, often accompanied by symptoms like cramps, nausea, dizziness, and fatigue. A provoking factor for this intradialytic hypotension (IDH) is an inability to cope with the prescribed fluid removal, leading to an extensive reduction in blood volume. Some patients are more susceptible, with cardiac (heart) dysfunction and anti-high blood pressure treatment being examples of significant risk factors. For patients who experience frequent IDH episodes it means distressing symptoms but also a risk of illness related to organ ischemia (lack of blood flow) during the IDH episodes. The Hemocontrol function of the Artis dialysis machine measures the blood volume reduction during dialysis and continuously adjusts to reduce the rate of IDH. The aim of this study is to find out what effect Hemocontrol has on the incidence of IDH and other symptoms of dialysis in Korean hypotension-prone HD patients.

Who can participate?
Hypotension-prone HD patients aged between 18 and 75

What does the study involve?
Over three study periods participants are treated with current best practice HD for 8 weeks (period A), with HD with Hemoscan blood volume monitoring for 2 weeks (period B0), and with Hemocontrol HD for 8 weeks (period B1). The incidence of hypotension is compared between Hemocontrol HD and current best practice HD.

What are the possible benefits and risks of participating?
There are no known risks to participants because all participants will be on hemodialysis as their usual practice.

Where is the study run from?
The study takes place at 9 hemodialysis rooms in hospitals in South Korea

When is the study starting and how long is it expected to run for?
July 2011 to November 2011

Who is funding the study?
Gambro Korea Ltd

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Hemo01_042011

Study information

Scientific Title
Clinical evaluation of Hemocontrol in hypotension-prone hemodialysis patients: a multicenter prospective cross-over study

Study objectives
Evaluate what effect an automatic blood volume controlled treatment approach (Hemocontrol) has on the incidence of intradialytic hypotension and other symptoms of dialysis, the change in blood pressure from pre to post dialysis, and the control of dry weight in Korean hypotension-prone hemodialysis (HD) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Seoul St Mary's Hospital, 07/08/2011, ref: CIRB-00039_23-01
All other centres will seek ethics approval before recruitment of the first participant

Study design
Prospective open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Comparing A) current best practice HD (baseline) with B) Hemocontrol HD, in an AB cross-over design.

Study period A (baseline): Current best practice HD 8 weeks evaluation
1. Regular treatment setup
2. Regular clinical assessment of dry weight
*Period A could be with any machine type (but it should be documented which machine)

Study period B0: HD with Hemoscan blood volume monitoring 2 weeks with Artis machine
This is a preparation phase for the Hemocontrol period, required to establish the patients individual blood volume/ ultrafiltration (BV/UF) volume values that are required as input to Hemocontrol
1. Hemoscan function activated
2. Constant UF rate and constant dialysis fluid sodium setting throughout the HD treatment
3. Assessment of the blood volume (BV) curve shape
4. Assessment of the BV/UF vol parameter required by Hemocontrol

Study period B1: Hemocontrol HD treatments 8 weeks evaluation with Artis machine
1. Hemocontrol activated throughout the period
2. Hemocontrol BV/UF vol parameter initially set as determined in period B0 and thereafter adjusted in accordance with Hemocontrol guidelines (see appendix to be prepared)
3. Hemocontrol Equivalent sodium (Na) parameter set individually to the same value as used for dialysis fluid Na in the baseline period-Is there any reference about standard Serum Sodium level
4. Hemocontrol Max UF Coefficient and Na Limits parameters set at 1.5 and Standard, respectively
5. Dry weight initially set as in baseline period and thereafter adjusted based on clinical assessments and the information provided by the Hemocontrol refill indicators

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Incidence rate of dialysis treatments affected by one or more symptomatic hypotensive episodes, comparing Hemocontrol HD to current best practice HD
2. Hypotensive episodes defined as a decrease in systolic BP >=20 mmHg or a decrease in mean arterial pressure (MAP) by >=10 mmHg that is associated with characteristic symptoms and requires nurse intervention by any type

Key secondary outcome(s))
1. Pre- and post-dialysis systolic and diastolic blood pressure (alternatively mean arterial blood pressure)
2. Post-dialysis body weight (dry weight)
3. Inter-dialytic weight gain
4. Symptoms during dialysis that appear without hypotension: muscular cramps, dizziness, nausea
5. Patients subjective assessment of tiredness after dialysis
6. Dialysis dose delivered Urea Reduction Ratio (URR)
7. Blood biochemistry data for sodium, calcium, phosphorus, potassium, hemoglobin, and albumin
8. 48hrs blood pressure (BP) monitoring (describe BP medications during monitoring)

Completion date
15/11/2011

Eligibility

Key inclusion criteria
1. Hypotension-prone patients, i.e. patients showing symptomatic hypotensive episodes in response to fluid removal by dialysis in 25% or more of treatments during 1 month preceding the study
2. Mostly showing an inter-dialytic weight gain of 1.5 kg or more
3. Age between 18 and 75 years
4. On dialysis for at least 3 months, on three dialysis per week schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. A regular pre-dialysis mean arterial blood pressure in supine position of <90 mmHg
2. Regular blood flow rate for dialysis lower than 200 ml/min
3. Ppre-dialysis hemoglobin level regularly above 13 g/dl
4. Treatment by hemodiafiltration (HDF)
5. Expected need for blood transfusions

Date of first enrolment
18/07/2011

Date of final enrolment
15/11/2011

Locations

Countries of recruitment
Korea, South

Study participating centre
Gambro Korea Ltd.
Seoul
Korea, South
135-090

Sponsor information

Organisation
Gambro Korea Ltd. (Korea, South)

ROR
https://ror.org/00y1hj465

Funder(s)

Funder type
Industry

Funder Name
Gambro Korea Ltd. (Korea, South) (Reference No.: Hemo01_042011)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/06/2014	Yes	No