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Assessment of plasma conductivity in Korean hemodialysis (HD) patients in relation to sodium and fluid status

Submission date
27/05/2013

Recruitment status
No longer recruiting

Registration date
05/06/2013

Overall study status
Completed

Last Edited
23/06/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hemodialysis is the process where a dialysis machine is used to purify the blood of a person whose kidneys are not working normally. The aim of this study is to gather information from Korean hemodialysis patients on how the change in plasma conductivity during dialysis relates to the patient's fluid gain up to the next dialysis session. Plasma conductivity is measured by the dialysis machine and reflects the presence of ions, mainly sodium and potassium. The study also looks at the relationship between plasma conductivity and the measured plasma sodium and potassium levels.

Who can participate?
Patients aged 18 or older with end-stage kidney disease undergoing hemodialysis

What does the study involve?
Participants follow their usual dialysis schedule during the study, and all the treatment parameters are unaffected by the study. Data is collected over 12 ordinary dialysis sessions, including plasma conductivity and body weight. There are no extra visits besides the usual dialysis treatments.

What are the possible benefits and risks of participating?
The expected benefits for the patient are small. However, the increased awareness of changes in plasma conductivity and plasma sodium in response to the prescribed dialysis fluid sodium level may lead to a more personalized sodium prescription by dialysis. The foreseeable risks of participating in this study are small and do not differ from those usually observed during hemodialysis treatment.

Where is the study run from?
1. Samsung Medical Center (South Korea)
2. Kangbuk Samsung Medical Center (South Korea)
3. Catholic University of Korea Incheon St. Mary's Hospital (South Korea)
4. Kangwon National University Hospital (South Korea)

5. Konkuk University Chungju Hospital (South Korea)
6. Catholic University of Korea, Daejeon St. Mary's Hospital (South Korea)
7. Hallym University Kangnam Sacred Heart Hospital (South Korea)
8. Inje University Sanggye Baik Hospital) (South Korea)

When is the study starting and how long is it expected to run for?
January 2013 to June 2013

Who is funding the study?
Gambro Korea Ltd (South Korea)

Who is the main contact?
Jungmin Im
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1503

Study information

Scientific Title
Assessment of plasma conductivity in Korean hemodialysis (HD) patients in relation to sodium and fluid status: a prospective, open-label, multicenter study

Study objectives

To demonstrate in prevalent Korean anuric dialysis patients that the change in plasma conductivity during dialysis, as measured by the Diascan tool, is related to the weight gain during the following interdialytic period (inter-dialytic weight gain).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Samsung Medical Center IRB, 07/02/2013, ref: SMC2012-12-099-001
2. Kangbuk Samsung Medical Center IRB, 12/02/2013, ref: KBC13020D
3.Catholic Univ. St'Mary Incheon Hospital IRB, 04/04/2013, ref: CIRB-00060_2-014
4. Kangwon National Univ. Hospital IRB, 05/02/2013, ref: KWNUH2013-01-003-001
5. Konkuk Univ. Chungju Hospital IRB, 19/02/2013, ref: 2013-005
6. Catholic Univ. St'Mary Daejeon hospital IRB, 04/04/2013, ref: CIRB-00060_2-013
7. Hallym University Kangnam Sacred Heart Hospital IRB, 28/02/2013, ref: 2013-01-11(701)
8. Inje University Sanggye Baik Hospital IRB, 13/02/2013, ref: SPIRB-13-009

Study design
Prospective open-label multicenter study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
End stage renal disease (ESRD)

Interventions
The patient will be on his/her ordinary dialysis schedule during the study period, and treatment parameters like session length, blood flow rate, dialyzer type and size, anticoagulation strategy, and ultrafiltration (UF) volume will be prescribed in the ordinary manner unaffected by the study. The subjects prescribed dialysis fluid composition should preferably be kept unchanged during the study period.

In addition to the enrollment visit, patient and treatment data collection will be done in conjunction with 12 ordinary dialysis sessions. There are no extra visits besides the usual dialysis treatments.

Total Duration of study treatment : 6 weeks per patient

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Initial and final plasma conductivity, as displayed by the Diascan monitoring tool, recorded in all mid-week dialysis sessions during the 6 week study period
2. Body weight post-dialysis for all mid-week dialysis sessions and pre-dialysis for all subsequent dialysis sessions during the 6 week study period

Secondary outcome measures
1. Initial and final plasma conductivity levels during the dialysis session
2. Plasma sodium levels pre- and post-dialysis
3. Plasma osmolarity level pre- and post-dialysis
4. Intradialytic change in plasma sodium
5. Dialysis fluid to plasma sodium gradient at start of dialysis
6. Body weight pre and post dialysis and pre dialysis at the following dialysis session
7. Need for saline infusion (isotonic saline or hypertonic solution) during the dialysis session
8. Recording of potential safety events

Overall study start date
29/01/2013

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. End stage renal disease (ESRD)
2. Male and female aged 18 or older
3. Treated in HD or HemoDiaFiltration (HDF) mode three times per week since at least 3 months
4. On stable dialysis prescription since at least 1 month (without major changes in dry weight, dialysis fluid conductivity/sodium level, dialyzer type, blood flow rate)
5. Available for treatment with Gambro dialysis machines equipped with the Diascan monitoring tool
6. Signed consent to participate in the study (informed consent)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
230

Key exclusion criteria
1. 24 hour urine volume production estimated to be >100 ml
2. Dialysis prescribed with varying dialysate sodium level (sodium profiling)
3. Considered unable to respond to thirst by free fluid intake
4. Regularly prescribed infusion of Na-containing fluids during or between dialysis session (e.g. saline to manage intradialytic hypotension)
5. Regularly prescribed infusion of albumin solution, e.g. to manage hypoalbuminemia or intradialytic hypotension
6. Pregnancy or planned pregnancy
7. Known hyperproteinemia or hyperlipidemia

Date of first enrolment
29/01/2013

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Korea, South

Study participating centre
Samsung Medical Center
Seoul
Korea, South
135-710

Sponsor information

Organisation
Gambro Korea Ltd. (Korea, South)

Sponsor details
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Korea, South
135-090

Sponsor type
Industry

Website
http://www.gambro.com

ROR
https://ror.org/00y1hj465

Funder(s)

Funder type
Industry

Funder Name
Gambro Korea Ltd (Korea, South)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration