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Comparison of acetic-free versus conventional dialysis fluid in patients with chronic renal failure

Submission date	Recruitment status	[_] Prospectively registered
28/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2013	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1485

Study information

Scientific Title
Biocompatibility of a new acetic free dialysis fluid (Honeycit) compared to conventional dialysis fluid (Selectbag® One) in an open, randomised, prospective, controlled crossover study

Study objectives
A new dialysis fluid containing citric acid has been developed. The safety and biocompatibility of citrate containing dialysate has earlier been investigated with positive results. The aim of this study is to verify the biocompatibility during 6 weeks use of the study product.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 28/10/2010

Study design
Prospective open label randomised active controlled crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic renal failure

Interventions
Patients will be randomised to receive dialysis with either
1. New acetic free dialysis fluid (Honeycit)
2. Conventional dialysis fluid (Selectbag® One)

Patients in each group will receive 6 weeks of treatment, followed by a 2 week wash out period, then crossover to the alternative treatment for a further 6 weeks.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure

Plasma concentration (P) of Advanced Glycation End products (AGEs), analysed by fluorescence (em 430/ex 350), pre- and post- each 6 week treatment phase

Secondary outcome measures

1. Safety:
1.1. Adverse effects (AE) / Severe adverse effects (SAE)
1.2. Plasma (P)-Parathyroid hormone (PTH)
1.3. P-Ionized-calcium
1.4. P-Citrate
1.5. Blood gas (pH, PO2, PCO2, Base excess)
1.6. Blood (B)-Complete Blood Count (Haemoglobin [Hb], Haematocrit [Hct], White Blood Count [WBC], Red Blood Count [RBC] and Platelets)
1.7. P-Electrolytes (sodium [Na], potassium [K], total calcium [tot-Ca], chlorine [Cl], urea and albumin)
1.8. Blood pressure and heart rate
2. Inflammation:
2.1. P- C-reactive Protein (CRP)
2.2. B- Interleukin (IL)-6
2.3. B- IL-1β
2.4. B- Tumour Necrosis Factor (TNF)-α
3. Coagulation:
3.1. B- Thrombin-Antithrombin (TAT)
3.2. B- Activated Partial Thromboplastin Time (APTT)
3.3. Visual rinse-back information and assessment
4. Additional exploratory parameters:
4.1. Biocompatibility:
4.1.1. Carboxymethyllysine (CML)
4.1.2. Pentosidine
4.1.3. Pentraxin-related protein (PTX3)
4.1.4. Glutathione (GSH/GSSG)
4.1.5. Malondialdehyde (MDA)
4.1.6. 8-Oxo-2'-deoxyguanosine (8-oxo-dG)
4.1.7. modified Advanced Oxidation Protein Product (mAOPP) (stress biomarker)
4.1.8 Total Aminothiols
4.2. Treatment parameters:
4.2.1. Treatment mode (HD/HDF)
4.2.2. Dialyser
4.2.3. Blood circuit and machine
4.2.4. Body weight before and after treatment
4.2.5. Treatment time
4.2.6. Blood flow rate
4.2.7. Dialysis flow rate
4.2.8. Ultra filtration rate and volume
4.2.9. Trans-Membrane Pressure (TMP)
4.2.10. Arterial and venous pressure
4.2.11. Accumulated blood volume and where applicable total infusion volume
4.2.12. Anticoagulation (type, dosage and administration) and potassium level. Diascan Kt/V

All outcomes will be assessed pre- and post- each 6 week treatment phase.

Overall study start date
17/01/2011

Completion date
27/05/2011

Eligibility

Key inclusion criteria
1. Chronic renal failure
2. Stable patients treated on Gambro Select® system (AK200S or AK200 Ultra S) 3 times/week for at least 4 weeks using SelectBag® One (Ca+1.5 mmol/l)
3. Patients treated in haemodialysis (HD) or Haemodiafiltration (HDF) mode with a blood flow rate between 250-400 ml/min during 4-5.5 hours
4. Patients treated with Gambro high flux filter; Polyflux 170H or Polyflux 210H
5. Signed consent to participate in the study (informed consent)
6. Patient aged 18 years or older, male or female
7. Haemoglobin 10 to 13.5 g/dl (haematocrit 30% to 40%)
8. Patients able to tolerate prescribed dialysis fluid with electrolyte concentrations as specified for the test device
9. Technical survival during study period as judged by study investigator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Known Human Immunodeficiency Virus (HIV), Hepatitis C or B Virus (HCV or HBV) infection (positive serology)
2. Patients with ionized-calcium value < 1.1 mmol/l
3. Patients unable to tolerate Citrate as judged by Investigator
4. Patients using Citrate anticoagulation in usual HD treatment
5. Pregnant / planning pregnancy and lactating women during study period
6. Patients with acute inflammatory or infectious event which, as judge by Investigator, may affect the safety of the patient and/or the result of the study
7. Patients with known haemodynamic instability that, as judged by the investigator, might cause clinical treatment problems

8. Chronic single needle dialysis
9. Participation in other studies during the study period that can affect the outcome of this study
10. Patients not considered compliant in following the study protocol, as judged by Investigator

Date of first enrolment
17/01/2011

Date of final enrolment
27/05/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Magistratsvägen 16
Lund
Sweden
SE-22010

Sponsor information

Organisation
Gambro Lundia AB (Sweden)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type

Industry

Funder Name
Gambro (Sweden)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/10/2013		Yes	No