

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

Submission date
28/10/2010

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
09/08/2011

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
25/10/2013

Condition category
Urological and Genital Diseases

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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-1 β
 - 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 Amino thiols
 - 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/05mw5ed57>

Funder(s)

Funder type

Industry

Funder Name

Gambro (Sweden)

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	09/10/2013		Yes	No