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Biocompatibility of a new haemodialysis concentrate containing gluconic and citric acid (Honeydew) compared to acetic acid (SelectBagOne®) and citric acid (Honeycit)

Submission date 28/12/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/02/2010	**Overall study status** Completed	
Last Edited 17/02/2010	**Condition category** 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
1476

Study information

Scientific Title
Biocompatibility of a new haemodialysis concentrate containing gluconic and citric acid (Honeydew) compared to acetic acid (SelectBagOne®) and citric acid (Honeycit) in an open, randomised, prospective, controlled and parallel-group study

Acronym
Honeydew III

Study objectives
To collect biocompatibility data on a new haemodialysis fluid (containing gluconic acid and citric acid) for scientific communication.

The primary objective is to investigate the biocompatibility of the new HD concentrate containing gluconic and citric acid during 8 weeks of HD treatment by comparing it with the HD concentrate with acetic acid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Lund pending approval as of 11/01/2010.

Study design
Open randomised prospective controlled parallel-group multicentre 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 the contact details below to request a patient information sheet

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

Interventions
For all treatment arms:
Starts with a 2-week run-in period for stabilisation (SelectBagOne®), followed by an 8-week treatment period with either of the following hemodialysis fluids:

1. Gluconic and citric acid (Honeydew), or
2. Citric acid (Honeycit), or
3. Acetate (SelectBagOne®)

No follow-up period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gluconic and citric acid (Honeydew), acetic acid (SelectBagOne®), citric acid (Honeycit)

Primary outcome measure
Plasma concentration of Advanced Glycation End products (AGE). Analysing method: Fluorescence (em 430/ex 350).

Sampling for all endpoints will be done at T0, T1 and T2:
T0: (baseline) sampling when entering into the randomised treatment-period
T1: sampling after 4 weeks in treatment-period
T2: sampling after 8 weeks in treatment-period

Secondary outcome measures
1. Plasma electrolytes (Na, K, Cl, i-Ca), blood glucose, plasma urea, blood haemostatic parameters (Hb, Hct, Lpk, Epk and Tpk) and blood gases but also blood pressure, heart rate, adverse events (AE)/serious adverse events (SAE), concomitant medication, patient and treatment parameters
2. Plasma and urine gluconate and plasma and urine citrate
3. Carboxymethyl lysine (CML), serum pentosidine
4. Blood glutathione (GSH, including oxidised glutathione [GSSG]), blood 8-iso-PGF2a (lipid peroxidation), serum modified advanced oxidative protein products [AOPP], blood total aminothiol (gamma glucys, GSH, cysgly, cys, hcy)
5. Plasma C-reactive protein (CRP), plasma tumour necrotising factor alpha (TNFa) and serum pentraxine-3
6. Blood activated clotting time (ACT) and blood thrombin-antithrombin III (TAT)

Sampling for all endpoints will be done at T0, T1 and T2:
T0: (baseline) sampling when entering into the randomised treatment-period
T1: sampling after 4 weeks in treatment-period
T2: sampling after 8 weeks in treatment-period

Overall study start date
15/04/2010

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Chronic renal failure
2. Stable patients treated 3 times/week for at least 1 month
3. Patients treated in HD mode with a blood flow rate between 250 - 400 ml/min during 4 - 5.5 hours
4. Patients treated with Gambro high flux filter (e.g. Polyflux 170H or Polyflux 210H)
5. Patients treated with Gambro AK200S or AK200 Ultra S with select system
6. Written consent to participate in the study (informed consent)
7. Patient aged 18 years or older, either sex
8. Vascular access able to deliver blood flow rate of greater than or equal to 250 ml/min
9. Haemoglobin 10 - 13.5 g/dl (haematocrit 30% to 40%)
10. Patients able to tolerate prescribed dialysis fluid with electrolyte concentrations as specified for the test device
11. 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
90 randomised patients

Key exclusion criteria
1. Known human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV) infection (positive serology)
2. Patients unable to tolerate citrate
3. Patients using citrate anticoagulation in usual HD treatment
4. Pregnant and lactating women
5. Patients with acute inflammatory or infectious event that, as judged by the investigator, may affect the safety of the patient and/or the results of the study
6. Patients with known haemodynamic instability that could cause, as judged by the investigator, clinical treatment problems
7. Chronic single needle dialysis
8. Participation in other studies during the study period that will affect the outcome of this study
9. Patients not considered compliant to follow the study protocol, as judged by investigator

Date of first enrolment
15/04/2010

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Njurkliniken
Lund
Sweden
221 85

Sponsor information

Organisation
Gambro Lundia AB (Sweden)

Sponsor details
Magistratsvägen 16
P.O. Box 10101
Lund
Sweden
220 10

Sponsor type
Industry

Website
http://www.gambro.com/se/

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Gambro Lundia AB (Sweden) (ref: 556057-7594)

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