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CLinical Evaluation of the AK-200 Ultra and oN-line HemoDiaFiltration with Bicarbonate Subsitution Fluid

Submission date	Recruitment status	[_] Prospectively registered
26/05/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2009	Urological and Genital Diseases	[_] Record updated in last year

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
N/A

Study information

Scientific Title

Acronym
CLEAN-HDF study

Study objectives
The CLEAN-HDF study is a randomized controlled trial comparing the performance of low-flux hemodialysis, high-flux hemodialysis and on-line hemodiafiltration with a cross over study design on a group of 48 ESRD patients using GAMBRO AK-200 Ultra generator. Research hypothesis are to demonstrate that mean % reduction of B2-microglobuline plasma concentration are superior in on-line hemodiafiltration compared to low- and high- flux hemodialysis and that the generator AK200 Ultra is capable of producing reliable sterile substitution fluid according to the European Pharmacopea

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Renal replacement therapy

Interventions
Randomised cross-over study of three hemodialysis modalities: low-flux haemodialysis, high-flux hemodialysis and on-line haemodiafiltration

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Mean % reduction of B2-microglobuline plasma concentration during a mid-week session

2. Substitution fluid analysis (microbiology: culture and endotoxins and biochemical content)

Secondary outcome measures
A variety of exploratory outcomes: biochemical [for example Kt/V, total urea, creatinine of B2-microglobulin clearance, pre-post study change in b2-microglobulin concentrations, CRP, etc], dialysis tolerance, quality of life, nutritional parameters, etc).

Overall study start date
01/06/2005

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Chronic end-staged renal diseased (ESRD) patients on haemodialysis

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Hemodialysis for less than 3 months
2. Current or recent hospitalisation (less than 6 weeks) prior to screening period
3. Dysfunctional or infected vascular access
4. Intolerance to high-flux hemodialyser
5. Intolerance to multi-vitamin supplement
6. Severe co-morbidities limiting expected life expectance to less than 6 months
7. History of severe congestive heart failure (New York Heart Association [NYHA] class III and IV)
8. Uncontrolled hypertension (HTN) (systolic blood pressure [BP] over 200 or diastolic over 110) during the two week screening period
9. Significant and instable hypotension (systolic BP less than 90 or greater than 2 hypotension episodes/dialysis session for more than 3 sessions) during the two week screening period
10. Use of midodrine
11. Hepatite B, C or human immunodeficiency virus (HIV) positive serologies
12. Presence of pure red cell aplasia (PRCA)
13. Pregnancy or lactating
14. Current participation (or for less than 3 months) in another intervention trial

15. Presence of psychiatric, dependance or any other health problems that may compromise the hability of the subject to signed the informed consent form and/or affect compliance to the study

Date of first enrolment
01/06/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Canada

Study participating centre
330 Université
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Sponsor information

Organisation
Beauséjour Medical Research Institute (L'Institut de Recherche Médicale Beauséjour) (IRMB) (Canada)

Sponsor details
37 Providence
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Sponsor type
Research organisation

ROR
https://ror.org/029tnqt29

Funder(s)

Funder type
Industry

Funder Name
Gambro (Canada)

Funder Name
Nephrology Department of the Beauséjour Regional Health Authority (Canada)

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