

Clinical Evaluation of the AK-200 Ultra and on-line HemoDiaFiltration with Bicarbonate Substitution Fluid

Submission date
26/05/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
15/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
14/09/2009

Condition category
Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

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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Moncton
Canada
E1C 2Z3

Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

1. Mean % reduction of B2-microglobuline plasma concentration during a mid-week session
2. Substitution fluid analysis (microbiology: culture and endotoxins and biochemical content)

Key secondary outcome(s)

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).

Completion date

30/06/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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 expectancy 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 ability 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
Moncton
Canada
E1C 2Z3

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration