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Evaluation of lifespan in AN69ST with two different heparinization strategies

Submission date	Recruitment status	[_] Prospectively registered
13/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/03/2008	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
1446

Study information

Scientific Title

Study objectives
Reduction of heparin dose in acute renal failure treated with hemodiafiltration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local research ethics committee, Göteborg, Sweden. Date of approval: 17/12/2007 (Dnr. 576-07)

Study design
Monocentric, open, randomised and controlled study with two parallel groups.

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 (in Swedish only)

Health condition(s) or problem(s) studied
Acute renal failure/ fluid overload

Interventions
The same dialysis membrane, AN69ST, will be used for both the intervention and control treatment. Two different heparinization strategies will be compared:

Control group (usual heparin doses): Bolus at start (between 1,000 IU - 2,500 IU) + usual infusion dose (10 IU/kg/h)
Intervention group (Reduction of heparin dose): No bolus at start + infusion decreased by 50% (5 IU/kg/h)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Filter lifespan, defined as the time period between patient's connection and filter disconnection due to filter clotting.

Secondary outcome measures
Adverse events, monitored for up to 24 days of treatment

Overall study start date
12/02/2008

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Patients requiring continuous renal replacement therapies (CRRT)
2. Aged 18 and over
3. Patients weighing 30-120 kg
4. Patients having signed a written consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44

Key exclusion criteria
1. History of heparin antibodies or heparin-induces thrombocytopenia
2. Known hypertensive to any dialysis membrane
3. Current enrolment in another trial which could impact the successful completion of this study
4. Patients under guardianship
5. Patient anticipated to require transportation outside the unit for diagnostic or therapeutic procedures in the coming first week .These patients can eventually be included in a later more stable phase
6. Unconscious patients for whom no relative or person of trust can give consent to treatment. In the absence of any relative or person of trust, the patient in question cannot be included in the study
7. Patient requiring anticoagulation for other indications e.g., valvular surgery or extracorporeal ventricular assist devices
8. Patients with active bleeding who does not require heparinization

Date of first enrolment
12/02/2008

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital
Gothenburg
Sweden
SE- 413 45

Sponsor information

Organisation
Gambro Lundia AB (Sweden)

Sponsor details
Clinical Trial Function
Clinical Affairs
P.O. Box 10101
Lund
Sweden
SE -220 10

Sponsor type
Industry

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

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Gambro Lundia AB (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