

Evaluation of lifespan in AN69ST with two different heparinization strategies

Submission date 13/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/03/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/03/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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-induced 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