

AN69 surface treated (ST) versus AN69 in continuous renal replacement therapy (CRRT): a prospective randomized cross-over study without heparin in the extracorporeal circuit

Submission date 04/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/10/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1441

Study information

Scientific Title

AN69 surface treated (ST) versus AN69 in continuous renal replacement therapy (CRRT): a prospective randomized cross-over study without heparin in the extracorporeal circuit

Study objectives

Evaluation of heparin-free treatment

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Continuous renal replacement therapy (CRRT)

Interventions

Please note that the first patient was recruited to this trial in November 2005 and the last patient completed the study in June 2007.

Each patient will be treated by maximum 4 filters (surface treated [ST] and non ST).

Randomisation of the sequence of treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary endpoint is filter lifespan, defined as the time period between patients connection and filter disconnection. Filter clotting will be detected by following transmembrane pressure (TMP) and Filter Pressure Drop (FPD). If the pressure changes are only temporary, treatment is continued. If they are permanent, the filter is discontinued with blood return.

Key secondary outcome(s)

Follow up of treatment safety: thrombopenia, bleeding episodes, transfusion requirement, treatment instability due to frequent filter changes.

Completion date

26/09/2006

Eligibility

Key inclusion criteria

1. Patients requiring CRRT
2. Patients aged 18 and over
3. Patients weighing 30-120 kg
4. Patients having signed a written consent (informed consent) to participate in the study or, in case the patient is unable to understand and/or sign the consent form, written consent from a relative or, failing which, a person of trust

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

39

Key exclusion criteria

1. Suspicion of heparin-induced thrombocytopenia
2. Pregnancy
3. Patients requiring therapeutic anticoagulation for other indications e.g. valvular surgery or extracorporeal ventricular assist devices
4. Patients under guardianship
5. Patients 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. Current enrolment in another trial which could impact the successful completion of this study
7. Unconscious patients for whom no relative or person of trust can give consent for treatment. In the absence of any relative or person of trust, the patient in question cannot be included in the study.

Date of first enrolment

26/09/2005

Date of final enrolment

26/09/2006

Locations

Countries of recruitment

Belgium

Study participating centre

University Hospital Gasthuisberg

Leuven

Belgium

3000

Sponsor information

Organisation

Gambro Industries (France)

ROR

<https://ror.org/01mgtdr23>

Funder(s)

Funder type

Industry

Funder Name

Gambro Industries

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/07/2012	29/10/2021	Yes	No