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# 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

**Registration date**
25/10/2005

**Last Edited**
29/10/2021

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

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

### Overall study start date
26/09/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40 (44 recruited as of end of study in June 2007)

### 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)

### Sponsor details
61 av Tony Garnier BP7315
Lyon
France
69357

### Sponsor type
Industry

### ROR
https://ror.org/01mgtdr23

## Funder(s)

### Funder type
Industry

### Funder Name
Gambro Industries

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |