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Prismaflex ST150 versus M150 in different treatment's conditions

Submission date	Recruitment status	[_] Prospectively registered
03/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/02/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2009	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
1465

Study information

Scientific Title

Prismaflex ST150 versus M150 in different treatment's conditions: a prospective randomised cross-over study

Study objectives
To validate the conclusion of a previous study: 'AN69 surface treated (ST) versus AN69 in continuous renal replacement therapy (CRRT): a prospective randomised cross-over study without heparin in the extracorporeal circuit' [ISRCTN58520610] (see http://www.controlled-trials.com/ISRCTN58520610).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commissie Medische Ethiek Van de Universitair Ziekenhuizen Kuleuven gave approval in January 2009

Study design
Prospective randomised cross-over study

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

Health condition(s) or problem(s) studied
Kidney disease

Interventions
1. Continuous veno-venous haemofiltration (CVVH) mode without heparin administration
2. Continuous veno-venous haemodiafiltration (CVVHDF) mode without heparin administration
3. Continuous veno-venous haemodiafiltration (CVVHDF) mode with heparin administration

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

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Prismaflex ST150, Prismaflex M150

Primary outcome measure
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).

Secondary outcome measures
Follow-up of adverse events (AE)/serious adverse events (SAE), assessed throughout the treatment.

Overall study start date
16/02/2009

Completion date
16/02/2010

Eligibility

Key inclusion criteria
1. Patients requiring continuous renal replacement therapy (CRRT)
2. Patients aged 18 and over, either sex
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
18

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.
8. Patients with high bleeding risk according to investigator and that cannot be treated with heparin. These patients should not be included in the therapy group continuous veno-venous haemodiafiltration (CVVHDF) with heparin administration.

Date of first enrolment
16/02/2009

Date of final enrolment
16/02/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Dept of Intensive Care
Leuven
Belgium
3000

Sponsor information

Organisation
Gambro Industries (France)

Sponsor details
7, Avenue Lionel Terray
Meyzieu
France
69883

Sponsor type
Industry

ROR
https://ror.org/01mgtdr23

Funder(s)

Funder type
Industry

Funder Name
Gambro Industries (France)

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