ISRCTN02674550 https://doi.org/10.1186/ISRCTN02674550

Pilot, prospective, multicentric, open study: use of a new Prismaflex filter (coated with heparin) without any addition of heparin in the extracorporeal circuit. Study with direct individual benefit.

Submission date	Recruitment status	[_] Prospectively registered
02/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/12/2006	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
1439

Study information

Scientific Title

Study objectives
Evaluation of heparin-free treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Committee for the Protection of Persons (CPP) on 06/12/2005, reference number 2005/063B

Study design
Pilot, prospective, multicentric, open study

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
Patients are treated with a maximum five filters.

Please note that the study period of this trial has been extended to December 2007.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Evaluation of filters lifespan in patients treated by CRRT with the new products without any addition of heparin in the extracorporeal circuit

Secondary outcome measures
Safety assessment of heparin-free treatment

Overall study start date
30/11/2005

Completion date
30/08/2006

Eligibility

Key inclusion criteria
1. Patients requiring Continuous Renal Replacement Therapy (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 written consent from a relative or, failing which, a person of trust in case the patient is unconscious

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. History of heparin antibodies or heparin-induced thrombocytopenia
2. Known hypersensitivity to any dialysis membrane
3. Pregnancy
4. Current enrolment in another trial which could impact the successful completion of this study
5. Patients under guardianship
6. Patients anticipated to require transportation outside the unit for diagnostic or therapeutic procedures in the coming first week
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
30/11/2005

Date of final enrolment
30/08/2006

Locations

Countries of recruitment
France

Study participating centre
Hôpital Edouard Herriot
Lyon
France
69437

Sponsor information

Organisation
Gambro Industries (France)

Sponsor details
61 Avenue Tony Garnier
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

IPD sharing plan summary
Not provided at time of registration