

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 02/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/12/2006	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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69437

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