# 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

#### Contact name

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#### Contact details

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## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

Safety assessment of heparin-free treatment

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

# 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

#### IPD sharing plan summary

Not provided at time of registration