

Evaluation of a new pre-heparinised filter: a multicentre, open, prospective pilot study

Submission date 13/11/2006	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 04/12/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 07/08/2008	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ 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

Protocol serial number
1422

Study information

Scientific Title

Study objectives

To collect data to support European Conformity (CE)-marking of product.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee in Brussels and Ethics Committee in Lyon, approval pending as of 20/11/2006.

Study design

Open, multicentre, prospective non-randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic renal failure

Interventions

1. Investigational product: HEP-AN69ST
2. Control product: AN69AT

This is a non-randomised study. All patients will have the following treatments:

Week one: Three treatments with AN69ST (with usual heparin dose in the ECC)

Week two: Three treatments with HEP-AN69ST with the same heparin dose in the ECC as in week one

Week three: Three treatments with HEP-AN69ST with a 50% decrease in the heparin dose compared with weeks one and two

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Heparin

Primary outcome(s)

Adverse events, particularly related to bleeding and premature clotting

Key secondary outcome(s)

1. Questionnaire to hospital staff regarding priming procedure
2. Dialysance-easurement
3. Rinse back evaluations

Completion date

30/04/2007

Eligibility

Key inclusion criteria

1. Patients suffering from chronic renal failure
2. Patients treated in Haemodialysis (HD) unit performed with or without heparin injection in the Extra Corporeal Circuit (ECC)
3. Patients treated three times a week with AN69ST for a minimum of one month
4. Patients 18 years or older
5. Patients with a well-functioning vascular access as judged by the investigator
6. Signed written informed consent to participate in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Patients with known allergy to heparin
2. Patients with acute inflammatory event that may affect, as judged by the investigator, the results of the study or the safety of the patients
3. Pregnant women, nursing mothers and women planning a pregnancy during the course of the study
4. Patients under guardianship
5. Patients participating in other studies that could interfere with the objectives of this study
6. Patients treated in single needle mode
7. Patients treated in HD with low molecular weight heparin injection in the ECC
8. Patients with catheter

Date of first enrolment

15/12/2006

Date of final enrolment

30/04/2007

Locations**Countries of recruitment**

Belgium

France

Sweden

Study participating centre
Clinical Affairs
Lund
Sweden
220 10

Sponsor information

Organisation
Gambro Industries (France)

ROR
<https://ror.org/01mgtdr23>

Funder(s)

Funder type
Industry

Funder Name
Gambro Industries (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration