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

Submission date	Recruitment status	[X] Prospectively registered
13/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2008	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
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Adverse events, particularly related to bleeding and premature clotting

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

Overall study start date
15/12/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
30

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)

Sponsor details
Clinical Affairs
61 avenue Tony Garnier
Lyon
France
FR-69357

Sponsor type
Industry

Website
http://www.gambro.com/start.aspx?id=752

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