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Evaluation of the biocompatibility of cartridge blood set versus standard blood line: A pilot monocentric open randomized and cross-over study

Submission date	Recruitment status	[X] Prospectively registered
09/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2019	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
NCT00804453

Secondary identifying numbers
1455

Study information

Scientific Title
Evaluation of the biocompatibility of cartridge blood set versus standard blood line: A pilot monocentric open randomized and cross-over study

Study objectives
Improvement of biocompatibility with cartridge blood set.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]) Sud-Est III Lyon, approved on 31/01/2008 (ref: 2007-A01253-50)

Study design
Open randomised cross-over monocentric pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic renal failure/ hemodialysis

Interventions
Control: 1 x HD treatment with standard blood line
Intervention: 1 x HD treatment with cartridge blood set

The participants who receive HD treatment with standard blood line first will have their second HD done using the cartridge blood set, and vice versa (cross-over). Therefore, each participant receives 1 x control and 1 x intervention treatment).

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Measurement of Thrombin-AntiThrombin (TAT) complex generation

Timepoints of measurement: T0 (before hemodialysis treatment starts), during hemodialysis treatment (at T1h, T2h, T3h, T4h) and just before hemodialysis stops.

Secondary outcome measures
1. Quality of restitution
2. Follow-up of adverse events (AEs)

Timepoints of measurement: T0 (before hemodialysis treatment starts), during hemodialysis treatment (at T1h, T2h, T3h, T4h) and just before hemodialysis stops.

Overall study start date
15/02/2008

Completion date
30/04/2008

Eligibility

Key inclusion criteria
1. Patients suffering from chronic renal failure
2. Patients treated in HemoDialysis (HD) performed with or without heparin injection in the Extra Corporeal Circuit (ECC) irrespective the type of heparin (UFH and LMWH)
3. Patients treated 3 times a week with high-flux membrane for a minimum of 3 months
4. Patients 18 years or older
5. Patients with a well-functioning vascular access as judged by the investigator
6. Patients with negative serologies (HIV, hepatitis)
7. Patients having signed written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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. Active malignant disease
4. Pregnant women, nursing mothers and women planning a pregnancy during the course of the study
5. Patients under guardianship
6. Patients participating in other studies that could interfere with the objectives of this study
7. Patients treated in single needle mode
8. Patients with catheter
9. Patients receiving Anti-Vit K drug

Date of first enrolment
15/02/2008

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
France

Study participating centre
Gambro Industries
Lyon
France
69357

Sponsor information

Organisation
Gambro (France)

Sponsor details
Clinical Affairs Department
61 Avenue Tony Garnier
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Lyon
France
69357

Sponsor type
Industry

Website
http://www.gambro.com/int/

ROR
https://ror.org/01mgtdr23

Funder(s)

Funder type
Industry

Funder Name
Gambro (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