

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

Submission date 09/01/2008	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 01/02/2008	Overall study status Completed	☐ Protocol
Last Edited 01/02/2019	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ 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

ClinicalTrials.gov (NCT)

NCT00804453

Protocol serial number

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)

Primary study design

Interventional

Study design

Open randomised cross-over monocentric pilot study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Gambro (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration