ISRCTN93952087 https://doi.org/10.1186/ISRCTN93952087

Pilot, prospective, multicentre, open and non-randomised study: definition of an index of AntiXa value at the end of haemodialysis treatment

Submission date
03/07/2008

Recruitment status
No longer recruiting

Registration date
25/07/2008

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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)
NCT00781690

Protocol serial number
1456

Study information

Scientific Title
-

Acronym
RHODES

Study objectives
Assessment of systemic heparin dose decrease during haemodialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Ethics Committee of Stockholm (Sweden) on the 13th June 2008 (ref: 2008/2:5)
2. Local ethics committee (CPP Est III) (France) on the 11th June 2008 (ref: 2008-A00348647)

Ethics approval pending from:
3. Italy: Not yet submitted
4. Germany: Not yet submitted

Study design
Prospective open non-randomised pilot multi-centre study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
There are three periods in this trial:

Period one: usual haemodialysis with usual heparin dose
Period two: participants will have a systematic decrease of heparin dosage during Evodial haemodialysis
Period three: participants will have a systematic decrease of heparin dosage with Evodial system

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

To collect data to define a statistical index of Anti Xa (SIAX) value, at the end of HD treatment, performed without any coagulation issues.

Key secondary outcome(s))
1. To compare the SIAX value according to the different study periods:
1.1. To compare the SIAX obtained with Evodial with the one obtained with usual haemodialyser
1.2. To compare SIAX obtained before and after the heparin dose decrease period
1.3. To compare the SIAX obtained after heparin dose decrease when using SMA blood lines in addition to Evodial haemodialyser
1.4. To compare the SIAX obtained before and after an additional heparin dose decrease period when using SMA blood lines in addition to Evodial haemodialyser
2. To assess the possibility to decrease heparin dose with Evodial
3. To assess the possibility of an additional heparin dose decrease when using SMA blood lines in addition to Evodial haemodialyser
4. To follow product's safety

Exploratory objectives:
5. To assess low-thrombogenicity of Evodial when decreasing heparin
6. To verify that there is no evidence of product efficacy decrease when decreasing heparin
7. To assess Anti Xa and aPTT kinetics according to the level of heparin dose decrease
8. To assess the quality of the restitution according to the level of heparin dose decrease

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Patients suffering from chronic renal failure
2. Patients treated in haemodialysis (HD) three times a week for at least 3 months, with a stable heparin dose and the same filter
3. Patients treated in 4 - 4.5 hours HD mode with a blood flow between 300 - 350 ml/min
4. Patients for whom either low molecular weight heparin (LMWH) (enoxaparin, nadroparin, tinzaparin) or unfractionated heparin (UFH) is used
5. Patients with a well-functioning vascular access as judged by the investigator
6. Patients treated either on AK, Innova or Integra dialysis machines equipped with ionic dialysance device
7. Patients older than 18 years, either sex
8. Patients with negative serologies (acquired immune deficiency syndrome [AIDS], hepatitis)
9. Patients having signed 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. Patient with heparin-induced thrombocytopenia (HIT) or known heparin allergy
2. Patient treated in HD in single needle mode
3. Patients with catheter
4. Patients with acute inflammatory event that may affect, as judged by investigator patients' safety or study results
5. Patients participating in other studies that could interfere with the objective of this study
6. Patients with active malignant disease
7. Patients receiving heparin outside dialysis treatment
8. Patients under guardianship
9. Pregnant women, nursing mothers and women planning a pregnancy during the course of this study
10. Patients with serious history of coagulopathy
11. Patients receiving Anti-Vitamin K medication
12. Patients receiving an association of anti-platelets agents
13. Patients with heparin dose that can not be reduced for technical reason (excluding patients receiving too low heparin dose with no possibility of further reduction)

Date of first enrolment
01/08/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
France

Germany

Italy

Sweden

Study participating centre
CHU Brabois Nancy
Vandoeuvre
France
54511

Sponsor information

Organisation
Gambro Lundia AB (Sweden)

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Gambro Lundia AB (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2003	14/02/2019	Yes	No
Results article	results	01/06/2008	14/02/2019	Yes	No
Results article	results	01/04/2013	14/02/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes