HepZero study: Heparin Free dialysis with Evodial: A prospective multicenter, open, randomized, controlled clinical study with parallel groups

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Primary objective:- To determine the effectiveness of Evodial, as compared with standard of care in terms of successful treatments during the first heparin free dialysis treatment. If the non-inferiority of Evodial is demonstrated, the superiority…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36007

Source
ToetsingOnline

Brief title
HepZero study

Condition

- Other condition

Synonym
'renal failure' - 'chronic end-stage renal disease'

Health condition

Chronic end-stage renal disease

Research involving

Human

Sponsors and support

Primary sponsor: Gambro Lundia AB
Source(s) of monetary or material Support: Gambro Lundia AB

Intervention

Keyword: Clotting, Pre-heparinized hemodialyzer

Outcome measures

Primary outcome

Evaluation of succes rates during the first heparin free dialysis treatment.

The first heparin free dialysis treatment will be considered successful when

there is :

- No complete occlusion of air traps or dialyzer rendering dialysis impossible

(grade 4 of the scale).

- No additional saline flushes to prevent clotting.

- No change of blood lines/ dialyzer because of clotting.

- No premature stop /early rinse-back due to clotting.

Evaluation of clotting in the air traps will be performed at each hour along

the dialysis session by using a semi quantitative scale described below:

- Grade 1: No detectable clotting

- Grade 2: Minimal clot formation (presence of fibrinous ring)

- Grade 3: Clot formation (up to 5 cm) but dialysis still possible

- Grade 4: Complete occlusion of air traps or dialyzer rendering dialysis

impossible

The evaluation (clotting scoring) will be performed hourly by two independent observers. In any cases, including a potential dispute between the two observers, the decision to stop the dialysis session must be made only by authorized and trained members of the medical team i.e. the principal investigator or registered co-investigator.

Secondary outcome

Evaluation of success rates during the second and the third consecutive heparin free dialysis treatment.

As for the first heparin free dialysis treatment, treatments will be considered successful when there is :

- No complete occlusion of air traps or dialyzer rendering dialysis impossible (grade 4 of the scale).
- No additional saline flushes to prevent clotting.
- No change of blood lines/ dialyzer because of clotting.
- No premature stop /early rinse-back due to clotting.

The evaluation (clotting scoring) will be performed hourly by two independent observers as for the first heparin free dialysis treatment described in section above regarding " Primary study parameters/outcome").

Efficacy assessment:

- The UF achieved and weight loss, urea and creatinine reduction rates and also

ionogram will be documented during all dialysis sessions.

Ease of use:

- To measure ease of use, frequency and remaining volume of saline flushes will

be documented.

Safety:

- The occurrence of AEs/SAEs during the study will be collected.

Study description

Background summary

Hemodialysis patients with an increased bleeding risk are usually dialysed with low-dose anticoagulation or without any anticoagulation, often in combination with *predilution flow* (NaCl 0.9 % 1-2 l/h). Unfortunately, such HD sessions are often complicated by clotting of the extracorporeal system resulting in blood loss and early termination of the dialysis session and, thus, inadequate volume and solute removal. More subtle clotting in a proportion of dialyser fibre bundles may further contribute to inefficient hemodialysis.

Gambro Lundia AB, sponsor of the study and manufacturer of medical devices for hemodialysis, has developed a new hemodialyzer called Evodial. This dialyzer is composed of a dialysis membrane grafted with heparin (no release of heparin in the blood). The grafted heparin keeps its anticoagulant properties therefore it allows a regional anticoagulation limited to the blood circuit and avoid flushing of the extracorporeal circuit during hemodialysis session to prevent clotting of dialyzer and blood lines. This dialyzer is a CE marked, commercialized for 2 years and used in many dialysis centers.

Clinical studies carried out in 2007 and 2009 have shown, among a population of chronic dialysis patients without hemorrhagic risks that Evodial dialyzer permitted dialysis session decreasing by about 50% the usual heparin doses. No unexpected adverse reactions occurred during these studies.

The purpose of the HepZero study is to show, during the first heparin free dialysis session, that results using Evodial dialyzer without saline rinsing during the session are not inferior to the usual rinsing technique using saline flushes with regard to the proportion of dialysis sessions performed until treatment duration schedule without massive clotting of the extracorporeal circuit.

Study objective

Primary objective:
- To determine the effectiveness of Evodial, as compared with standard of care in terms of successful treatments during the first heparin free dialysis treatment.

If the non-inferiority of Evodial is demonstrated, the superiority of Evodial over standard of care will be tested.

Secondary objectives:
- To compare the success rate during the 2nd and 3rd consecutive heparin free treatment with Evodial to standard of care.
- To compare clotting grading in air traps during all treatments with Evodial versus standard of care.
- To assess the efficacy of heparin free dialysis treatment with Evodial vs. standard of care.
- To assess the easy of use of heparin free treatment with Evodial.
- To assess the safety of heparin free treatment with Evodial vs. heparin free treatment with standard therapy.

Study design

Prospective, multicenter, open, controlled, randomized clinical study with two parallel groups.

Intervention

Two types of therapies will be evaluated in parallel:
- Control Group: Heparin free hemodialysis treatment according to standard of care.
- Study Group: Heparin free hemodialysis treatment with Evodial (study product).

All enrolled patients in the study will be treated during a maximum of 3 heparin free dialysis treatments

Study burden and risks

Foreseeable risks for the patients included in this clinical study do not differ from those usually observed during this type of treatment.

No additional risk directly related to the use of the product can be objectively foreseen.

For all patients, a very close care will be performed:
- follow-up of clotting in the air traps every hour during the dialysis session, that could be considered as a benefit.
- For the patients randomized to the study product (Evodial dialyzer) it could be expected that the treatment may be superior to the standard care heparin free treatment, considering clotting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients requiring heparin free dialysis treatments on nephrologists' prescription.
2. Chronic end-stage renal disease (ESRD) patients treated by maintenance hemodialysis for at least 3 months.
3. Patients with a well functioning blood access that can allow a blood flow of at least 250 ml/min.
4. Patients aged 18 years or more.
5. Written consent to participate in the study;Patients that have already been treated with heparin free hemodialysis can be included into the study: first treatment meaning first treatment evaluated when patient is enrolled in the study.
Patients with a central venous catheter locked by heparin can be included in the study but a particular attention has to be paid to the sucking of heparin and the rinsing of catheter before starting the hemodialysis treatment.

Exclusion criteria

1. Patients in ICU (intensive care unit) setting.
2. AKI (acute kidney injury) patients.
3. Patients dialyzed in self care, satellite HD units.
4. Patients treated in single needle mode.
5. Known contraindication for heparin (HIT type II).
6. Patients requiring blood and other labile blood producs (i.e fresh frozen plasma, platelets, etc).
7. Patients receiving oral anticoagulants (including anti-vitamin K).
8. Patients receiving a combination (e.g. aspirin and clopidogrel) of anti-platelets agents
9. Patients treated with unfractionated or low molecular weight heparin beside the dialysis treatment to prevent deep vein thrombosis.
10. Pregnant/planning pregnancy and lactating women during the study period.
11. Adults patients protected by law.
12. Patients that are not affiliated to health insurance system.
13. Participation in other interventional studies during the study period.
14. Patients that have already been included in this study.

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2011
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-10-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Clin.trial.gov.
CCMO	NL36003.042.11