

Product safety study for a citrate calcium anticoagulation system

Submission date 04/02/2009	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 27/02/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 27/02/2009	Condition category Urological and Genital Diseases	☐ 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

Study information

Scientific Title
Product safety study for a citrate calcium anticoagulation system: an interventional single-arm open-label trial

Study objectives
Primary goal of the study is the proof of functionality and safety of a algorithm for automated software controlled citrate-calcium anticoagulation. The hypothesis of the authors is that the specification of a target calcium value in the anticoagulated extracorporeal circuit is associated with a high functionality and a high safety using a citrate calcium anticoagulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

To be submitted to the Ethics Committee of Upper Austria, Wagner Jauregg Mental Health Hospital as of 04/02/2009.

Primary study design

Interventional

Study design

Interventional single-arm open-label trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic dialysis

Interventions

Regional anticoagulation with trisodium citrate and substitution with calcium chloride. Five treatments per patient over 2 weeks, with a duration of 4 hours per treatment planned.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The following will be assessed at baseline, after 15 minutes and then every 60 minutes during treatment (maximum treatment duration is 4 hours):

1. Evaluation of the effectiveness of anticoagulation based on coagulation parameters
2. Time dependency of citrate and calcium values in the extracorporeal circuit
3. Anticoagulation state in the extracorporeal circuit
4. Citrate and calcium level in the patients blood

Key secondary outcome(s)

The following will be assessed at baseline and end of each treatment period: D-Dimer, Mg^{2+} and sodium concentration

Completion date

31/08/2009

Eligibility**Key inclusion criteria**

1. Both males and females, age: 19 to 65 years
2. Chronic dialysis patients
3. Haematocrit (Hkt): 30 bis 45 %

4. Ca²⁺: 1.0-1.30 mmol/l

5. Weight: >60 kg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. High risk of bleeding, platelets count <40,000/ μ l
2. Haemoglobin <9 g/dl
3. Alkalosis pH >7.50
4. Acidosis pH <7.35
5. Liver insufficiency
6. Respiratory insufficiency
7. Patients with cardiovascular problems
8. Oral anticoagulants
9. Hepatitis C, B, HIV patients

Date of first enrolment

01/05/2009

Date of final enrolment

31/08/2009

Locations

Countries of recruitment

Austria

Study participating centre

Dr.-Karl-Dorrek-Str. 30

Krems

Austria

3500

Sponsor information

Organisation

Danube University Krems (Austria)

ROR

<https://ror.org/03ef4a036>

Funder(s)**Funder type**

University/education

Funder Name

Danube University Krems (Austria)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration