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Product safety study for a citrate calcium anticoagulation system

Submission date	Recruitment status	[X] Prospectively registered
04/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2009	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

Protocol serial number
N/A

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.

Study design
Interventional single-arm open-label trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic dialysis

Interventions
Regional anticoagulation with trinatrium 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 extracorporal circuit
3. Anticoagulation state in the extracorporal 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, Mg2+ 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, pallets count <40,000/µl
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 anticoagulans
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