

# Product safety study for a citrate calcium anticoagulation system

<b>Submission date</b> 04/02/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2009	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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3500

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **Secondary study design**

Other

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Chronic dialysis

### **Interventions**

Regional anticoagulation with trinitrium 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 measure**

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

### **Secondary outcome measures**

The following will be assessed at baseline and end of each treatment period: D-Dimer, Mg<sup>2+</sup> and sodium concentration

### **Overall study start date**

01/05/2009

### **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. Ca<sup>2+</sup>: 1.0-1.30 mmol/l
5. Weight: >60 kg

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

14

### **Key exclusion criteria**

1. High risk of bleeding, platelets count <40,000/ $\mu$ 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)

**Sponsor details**

Dr.-Karl-Dorrek-Str. 30

Krems

Austria

3500

**Sponsor type**

University/education

**Website**

<http://www.donau-uni.ac.at>

**ROR**

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

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Danube University Krems (Austria)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration