ISRCTN31779998 https://doi.org/10.1186/ISRCTN31779998

Safety of citrate calcium anti-coagulation system and its use for liver insufficiency

Submission date 05/09/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/11/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/04/2017	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Blood purification can be done to help critical illnesses such as liver cancer as the liver is unable to remove toxins from the blood. It is similar to kidney dialysis, where the blood is pumped out of the body to be filtered by a machine and then pumped back to the body. However, when this is done it is usually requires an anticoagulation agent to prevent clotting. Research has developed a new algorithm (a process or set of rules in calculations) for citrate calcium anticoagulation in blood purification systems done outside of the body. The algorithm targets a certain ionized calcium concentration before the blood is filtered. This ensures sufficient levels of anticoagulation during the entire filtration process, as blood can be come into contact with foreign materials or air. The aim of this study is to see if this algorithm for anticoagulation is successful with patients who have chronic liver failure.

Who can participate?
Adults aged 18 to 75 years old with chronic liver disease.

What does the study involve?
Participants are treated two times with the FRESENIUS PrometheusT system (a blood filtration system) in combination with a developed citrate calcium anticoagulation system/algorithm. This occurs for around six hours. Participants are assessed at the beginning of the study, after 15 minutes and every 60 minutes during treatment to measure the level of ionized calcium in their body and in the filtration system.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University Hospital Graz (Austria)

When is the study starting and how long is it expected to run for?
January 2013 to August 2013.

Who is funding the study?
Center for Biomedical Technology, Danube University Krems (Austria)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CIP V1.0

Study information

Scientific Title
Product safety study for a citrate calcium anti-coagulation system and its application for liver insufficiency

Study objectives
Specification of a target calcium value in the anticoagulated extracorporeal circuit is associated with a high functionality and high safety using a citrate calcium anticoagulation.

The aim is to gain proof of functionality and safety of an algorithm for automated software controlled regional citrate-calcium anticoagulation applied to patients with liver insufficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical University Graz Ethics Committee, Austria

Study design
Interventional single-arm open-label trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Liver insufficiency

Interventions
Regional anticoagulation with trinatrium citrate and substitution with calcium chloride. Two treatments per patient, with a duration of 6 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 6 hours):
1. Evaluation of the ionized calcium level in the extracorporeal circuit
2. Evaluation of the ionized calcium level in the patient

Key secondary outcome(s))
The following will be assessed at baseline, after 15 minutes and then every 60 minutes during treatment (maximum treatment duration is 6 hours):
1. Citrate
2. iMg
3. Total Mg
4. Total calcium
5. Activated clotting time (ACT)

The following will be assessed at baseline and end of each treatment period:
1. Blood count
2. Albumin
3. Total protein

Completion date
31/08/2013

Eligibility

Key inclusion criteria
1. Both males and females with age: 18-75 years
2. Serum Bilirubin > 5 mg/dL (more than 72 h)
3. Model for End Stage Liver Disease (MELD) > 30 (more than 72 h) or
4. Therapeutic resistant hepatic encephalopathy ≥ II° or
5. Therapeutic resistant kidney failure (requiring dialysis) or

6. Therapeutic resistant alcoholic hepatitis or
7. Therapeutic resistant pruritus [Visual Analogue Scale (VAS) > 7]

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. INR > 3
2. Thrombocytes < 30,000
3. Multiorgan failure (liver and > 3 organs)
4. M ean arterial pressure (MAP) < 55 mmHg
5. Acute bleeding (>4 Erythrocyte concentrates in the last 24 hours)
6. Extra hepatic cholestasis

Therapeutic resistance:
1. Hepatic Encephalopathy: Lactulose 60g/d and Ornithin-Aspartate 20g/d i.v. within 72h
2. Kidney failure: volume support albumin 1g/kg-KG, Terlipressin (3 mg/d) within 72h
3. Alcoholic hepatitis: Prednislon 40 mg within 7 days and Lille Score >0.45
4. Pruritus: Cholestyramin 8g and Naltrexone 50 mg within 4 weeks

Date of first enrolment
01/01/2013

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
Austria

Study participating centre
Danube University Krems
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