# Prismaflex ST150 versus M150 in different treatment's conditions

Submission date	Recruitment status	Prospectively registered
03/02/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
24/02/2009	Completed	Results
Last Edited	Condition category	Individual participant data
24/02/2009	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

#### Contact name

Prof Marie Schetz University Hospital Gasthuisberg

#### Contact details

Dept of Intensive Care Herestraat 49 Leuven Belgium 3000

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** 1465

# Study information

Scientific Title

Prismaflex ST150 versus M150 in different treatment's conditions: a prospective randomised cross-over study

#### **Study objectives**

To validate the conclusion of a previous study: 'AN69 surface treated (ST) versus AN69 in continuous renal replacement therapy (CRRT): a prospective randomised cross-over study without heparin in the extracorporeal circuit' [ISRCTN58520610] (see http://www.controlled-trials.com/ISRCTN58520610).

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Commissie Medische Ethiek Van de Universitair Ziekenhuizen Kuleuven gave approval in January 2009

#### Study design

Prospective randomised cross-over study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

## 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

Kidney disease

#### Interventions

- 1. Continuous veno-venous haemofiltration (CVVH) mode without heparin administration
- 2. Continuous veno-venous haemodiafiltration (CVVHDF) mode without heparin administration
- 3. Continuous veno-venous haemodiafiltration (CVVHDF) mode with heparin administration

Each patient will be treated by a maximum of 4 filters (surface treated [ST] and non-ST).

#### Intervention Type

Drug

#### Phase

Phase IV

#### Drug/device/biological/vaccine name(s)

Prismaflex ST150, Prismaflex M150

#### Primary outcome measure

Filter lifespan, defined as the time period between patients connection and filter disconnection. Filter clotting will be detected by following transmembrane pressure (TMP) and Filter Pressure Drop (FPD).

#### Secondary outcome measures

Follow-up of adverse events (AE)/serious adverse events (SAE), assessed throughout the treatment.

#### Overall study start date

16/02/2009

#### Completion date

16/02/2010

# Eligibility

#### Key inclusion criteria

- 1. Patients requiring continuous renal replacement therapy (CRRT)
- 2. Patients aged 18 and over, either sex
- 3. Patients weighing 30 120 kg
- 4. Patients having signed a written consent (informed consent) to participate in the study or, in case the patient is unable to understand and/or sign the consent form, written consent from a relative or, failing which, a person of trust

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

18

#### Key exclusion criteria

- 1. Suspicion of heparin-induced thrombocytopenia
- 2. Pregnancy
- 3. Patients requiring therapeutic anticoagulation for other indications e.g. valvular surgery or extracorporeal ventricular assist devices
- 4. Patients under quardianship
- 5. Patients anticipated to require transportation outside the unit for diagnostic or therapeutic

procedures in the coming first week. These patients can eventually be included in a later more stable phase.

- 6. Current enrolment in another trial which could impact the successful completion of this study 7. Unconscious patients for whom no relative or person of trust can give consent for treatment. In the absence of any relative or person of trust, the patient in question cannot be included in the study.
- 8. Patients with high bleeding risk according to investigator and that cannot be treated with heparin. These patients should not be included in the therapy group continuous veno-venous haemodiafiltration (CVVHDF) with heparin administration.

# Date of first enrolment

16/02/2009

Date of final enrolment 16/02/2010

# Locations

**Countries of recruitment**Belgium

Study participating centre Dept of Intensive Care Leuven Belgium 3000

# Sponsor information

## Organisation

Gambro Industries (France)

#### Sponsor details

7, Avenue Lionel Terray Meyzieu France 69883

## Sponsor type

Industry

#### **ROR**

https://ror.org/01mgtdr23

# Funder(s)

Funder type Industry

**Funder Name**Gambro Industries (France)

# **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