ISRCTN39140035 https://doi.org/10.1186/ISRCTN39140035

Ex vivo microbiological assessment of an anti-biofilm catheter in acute dialysis application

Submission date	Recruitment status	[_] Prospectively registered
30/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/09/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2019	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00621114

Secondary identifying numbers
Study No 2007_MBR_003

Study information

Scientific Title
Ex vivo microbiological assessment of an anti-biofilm catheter in acute dialysis application

Study objectives
The clinical study aims at providing further data on antimicrobial efficiency and a supposed additional preventive effect on catheter-related infections of a catheter with antibacterial surface coating in comparison to standard catheters without coating but with identical design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval was granted by the local medical ethics committee (Ethikkommission der Medizinischen Fakultat der Eberhard-Karls-Universitat und am Universitatsklinikum Tubingen) on 25th July 2007 (ref:154/2007MPG1).

Study design
Prospective, randomised, single-centre, clinical study with 2 parallel patient groups (A and B) after prior sub-group stratification.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Renal disease

Interventions
Commercially available catheters will be used; the design will not be blinded. Catheters will be placed according to a defined protocol. The investigator selects the appropriate catheter length for each patient.

Type X: Standard double lumen catheter without coating: commercially available CE certified GamCath® catheter (Gambro Kathetertechnik Hechingen, Germany), Product codes: GDHK-1315J (outer diameter 13 French, length 15 cm, curved extension lines), GDHK-1320J (outer diameter 13 French, length 20 cm, curved extension lines)

Type Y: Double lumen catheter with bismuth-containing coating: commercially available, CE certified GamCath Dolphin® Protect catheter (Gambro Kathetertechnik Hechingen, Germany) with similar design and measures as the standard catheter, but with antibacterial coating, Product codes: MC-GDHK-1315J (outer diameter 13 French, length 15 cm, curved extension lines), MC-GDHK-1320J (outer diameter 13 French, length 20 cm, curved extension lines).

Catheters will be removed based on clinical indication; therefore there is no exact duration of treatment. There will be no follow-up blood investigations for the patient. The maximal observation period is 29 days.

Used catheters and arterial and venous rinsing fluids will be analysed for bacterial colonisation. A cut-off 100 CFU/mL will be defined as positive. Further characterisation of bacteria will be performed with focus on genetic variations of bacteria that might be attributed to inhibition or resistance mechanisms on the catheters.

Citrate plasma and lock solution samples will be analysed for bismuth concentrations by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). Routine clinical laboratory data will be analysed according to local clinical laboratory routine.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Bacterial colonisation of the catheter surface, analysed after removal of the catheter. A cut-off 100 CFU/mL will be defined as positive
2. Bismuth content in plasma and lock solution will be analysed before catheter placement, once weekly pre-dialysis and once at explantation

Secondary outcome measures
1. Catheter patency (indirect measure: venous and arterial pressure differences)
2. Catheter dwell time
3. Exit site appearance
4. Blood parameters

Secondary outcome measured will be documented at routine sampling.

Overall study start date
08/08/2007

Completion date
31/03/2008

Eligibility

Key inclusion criteria

1. Need for extracorporeal renal replacement therapy (acute and chronic renal failure)
2. Anticipated duration of dialysis therapy less than or equal to 30 days
3. Age between 18 and 85 years
4. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
69 patients with need for renal replacement therapy will be included in the study in a first approach.

Key exclusion criteria
1. Known Hepatitis B Virus (HBV)/Hepatitis C Virus (HCV)/Human Immunodeficiency Virus (HIV) infection
2. Known pregnancy

Date of first enrolment
08/08/2007

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
Germany

Study participating centre
Dr. med. Bjorn Friedrich
Tubingen
Germany
72076

Sponsor information

Organisation
Gambro Dialysatoren GmbH (Germany)

Sponsor details
Holger-Crafoord-Str. 26
Hechingen
Germany
72379

Sponsor type
Industry

Website
http://www.gambro.com/Portal.aspx?id=8644

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Dialysatoren GmbH (Germany) - grant

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) - Activities are part of the BMBF BioProfile project "Antibakterielle und biofunktionale Oberflachen fur extrakorporale sowie zelltherapeutische Verfahren" (ref: Forderkennzeichen 0313648)

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