ISRCTN93939200 https://doi.org/10.1186/ISRCTN93939200

Clinical assessment of a new catheter surface coating with antimicrobial properties: efficacy and effect of intensive catheter and exit site care education

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
14/02/2019	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

Contact name
Prof Dr. med. C. Erley

Contact details
Dr. med. B. Bader
St. Joseph-Krankenhaus
Baumerplan 24
Berlin
Germany
12101

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00621712

Secondary identifying numbers
Study No 2007_MBR_001

Study information

Scientific Title
Clinical assessment of a new catheter surface coating with antimicrobial properties: efficacy and effect of intensive catheter and exit site care education

Study objectives
Efficacy of a catheter with antibacterial surface coating in preventing central venous catheter-related infection in comparison to standard catheters without coating but with identical design, and effect of an intensive hygiene and catheter care education of the nursing staff on preventing central venous catheter-related infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval was granted by the Freiburger Ethikkommission International on 23rd April 2007 (ref: FECI code 07/1371). Furthermore, the study was submitted to the Local Ethics Committee: Charite - Universitatsmedizin Berlin Ethikkommission for consultation according to physicians professional regulations.

Study design
Prospective, randomised, single-centre, double-blind clinical study with two 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)
Treatment

Participant information sheet

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

Interventions
A prospective, randomised, single-centre, double-blind clinical study with two parallel patient groups (A and B) will be conducted. All patients will be examined for nasal Methicillin Resistant Staphylococcus Aureus (MRSA) carriage at inclusion into the study.

Stratification for the following subgroups wil be performed:
1. MRSA positive patients
2. MRSA negative patients
3. Patients with unknown MRSA status

Patients in group A will be provided with a commercially available and CE certified standard double lumen catheter without surface coating (GamCath® catheter, No. CE 76891). Patients in group B will be treated with a commercially available and CE certified double lumen catheter with a new antibacterial bismuth-containing surface coating (GamCath Dolphin® Protect, No. CE 90671).

In study phase I including 90 patients, the study will be conducted without additional hygiene training. Catheter and exit site care will be provided according to the standard procedures in the study centre. In study phase II, which will start after an intensive education of catheter care and hygiene for the nursing staff, another 90 patients will be included.

Study endpoints are bacterial colonisation after removal of the catheter (primary endpoint), surface deposits of thrombogenic activity (indirect measure: venous and arterial pressure differences), catheter survival, exit site appearance and blood parameters. Additionally, reasons for catheter removal will be precisely documented and analysed.

The following parameters will be documented:
1. The patient's medical history
2. Catheter handling during insertion
3. Catheter manipulations
4. Care of insertion site
5. Bloodstream and exit site infections
6. Heparin dose
7. Blood flow rate during dialysis
8. Venous and arterial pressures during dialysis
9. Body temperature
10. Treatment duration
11. Blood counts: blood analysis once weekly at start of dialysis sessions
12. Coagulation parameters Partial Thromboplastin Time (PTT), Anti-Thrombin III (AT III) and Procalcitonin (PCT): blood analysis once weekly at start of dialysis sessions
13. C-Reactive Protein (CRP) and fibrinogen: blood analysis at start of each dialysis session
14. Bismuth analysis in plasma before implantation of the catheter, at start and end of the first dialysis session, once weekly at start of the following dialysis sessions and at explantation of the catheter
15. Bismuth analysis from the lock-solution before start of each dialysis treatment
16. Number of treatments before catheter removal
17. Catheter dwell time
18. Detailed description of reasons for catheter removal
19. Catheter handling during removal

Used catheters and arterial and venous rinsing fluids will be analysed for bacterial contamination. Citrate plasma and lock solution samples will be analysed for bismuth concentrations by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). Blood samples for analysis in the study centre will be taken and analysed according to the local routine procedures (blood counts, PTT, AT III, PCT, fibrinogen).

The maximal observation period per patient is 29 days.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Bacterial colonisation of the catheter surface.

The time points of catheter analysis cannot be given exactly as these analyses are done after removal of the catheter and removal is determined by medical indication not influenced by the study protocol. The other sampling points and number of analyses are also depending on the individual patients treatment regimen. The maximal observation period is 29 days.

Secondary outcome measures
1. Surface deposits of thrombogenic activity
2. Catheter survival
3. Exit site appearance
4. Blood parameters:
4.1. Blood counts: blood analysis once weekly at start of dialysis sessions
4.2. Coagulation parameters PTT, AT III and PCT: blood analysis once weekly at start of dialysis sessions
4.3. CRP and fibrinogen: blood analysis at start of each dialysis session
4.4. Bismuth analysis in plasma before implantation of the catheter, at start and end of the first dialysis session, once weekly at start of the following dialysis sessions and at explantation of the catheter
4.5. Bismuth analysis from the lock-solution before start of each dialysis treatment

The time points of catheter analysis cannot be given exactly as these analyses are done after removal of the catheter and removal is determined by medical indication not influenced by the study protocol. The other sampling points and number of analyses are also depending on the individual patients treatment regimen. The maximal observation period is 29 days.

Overall study start date
10/09/2007

Completion date
31/01/2009

Eligibility

Key inclusion criteria
1. Need for extracorporeal renal replacement therapy (acute and chronic renal failure)
2. Age over 18 years
3. Written informed consent
4. Needed catheter length 15 cm or 20 cm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
180

Key exclusion criteria
1. Known infectivity with Hepatitis B Virus (HBV)/Hepatitis C Virus (HCV)/Human Immunodeficiency Virus (HIV)
2. Any infection associated with one or more positive blood cultures within 10 days prior to catheter implantation
3. Bacteremia with a former catheter within 10 days prior to catheter implantation
4. Known pregnancy
5. Lactation
6. Participation in another clinical study during the preceding 30 days

Date of first enrolment
10/09/2007

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
Germany

Study participating centre
Dr. med. B. Bader
Berlin
Germany
12101

Sponsor information

Organisation
Gambro Dialysatoren GmbH (Germany)

Sponsor details

Holger-Crafoord-Str. 26
Hechingen
Germany
72379

Sponsor type
Industry

Website
http://www.gambro.com

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Dialysatoren GmbH (Germany)

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