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Clinical assessment of a new catheter surface coating with antimicrobial properties: safety - handling - efficacy

Submission date
17/03/2006

Registration date
24/03/2006

Last Edited
24/03/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Protocol serial number
2005-MBR-001

Study information

Scientific Title

Acronym
Care BioBac

Study objectives
Show that safety, handling and efficacy of a new temporary hemodialysis catheter with antibacterial/anti-biofilm coating is equal or superior compared to standard catheters of same type

Ethics approval required
Old ethics approval format

Ethics approval(s)
Primary vote given by Charite, Berlin on 08/03/2004, reference number: 30/2004; secondary votes given by Arztekammer Westfalen-Lippe on 04/05/2004, reference number: 4/134 and Technical University Munich on 02/06/2004, reference number: 1080/04.

Primary study design
Interventional

Study design
Controlled, randomised, 2 parallel groups, multicenter

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
End-stage renal disease patients with need for a temporary hemodialysis catheter

Interventions
Comparison of standard temporary hemodialysis catheter with a new catheter with antibacterial /anti-biofilm coating

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Safety (early removal due to catheter failure)
2. Handling (implantation, removal)
3. Efficacy (hemodialysis blood flow rate, pressure)

Key secondary outcome(s)
1. Frequency of exit site and catheter-related bloodstream infections
2. Bacterial growth on the catheter
3. Inflammatory and coagulation parameters in plasma

Completion date

01/07/2006

Eligibility

Key inclusion criteria
1. Need for renal replacement therapy
2. Age ≥18 years
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Known acute hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV)
2. Age >75 years
3. Any infection associated wtih one or more positive blood cultures within 10 days prior to planned implantation
4. Any bacteremia associated with a previous catheter
5. Known pregnancy
6. Hospitalisation for more than 14 days
7. Respiratory assist
8. Use of antibiotics
9. Participation in another study during the preceding 30 days

Date of first enrolment
24/05/2004

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Germany

Study participating centre
Charité Campus Virchow-Klinikum
Berlin
Germany
13353

Sponsor information

Organisation
Gambro Corporate Research (Germany)

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Corporate Research

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration