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

Submission date	Recruitment status	Prospectively registered
17/03/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/03/2006	Completed	Results
Last Edited	Condition category	Individual participant data
24/03/2006	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

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Contact details

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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.

Study design

Controlled, randomised, 2 parallel groups, multicenter

Primary study design

Interventional

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

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

Αll

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