

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

Submission date 17/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 24/03/2006	Overall study status Completed	☐ Protocol
Last Edited 24/03/2006	Condition category Urological and Genital Diseases	☐ 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.

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

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 with 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