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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
Prof Ralf Schindler

Contact details
Charité Campus Virchow-Klinikum
Innere Medizin
Nephrologie und Internistische Intensivmedizin
Augustenburger Platz 1
Berlin
Germany
13353
ralf.schindler@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
1. Frequency of exit site and catheter-related bloodstream infections
2. Bacterial growth on the catheter
3. Inflammatory and coagulation parameters in plasma

Overall study start date
24/05/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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)

Sponsor details
Holger-Crafoord Street 26
Hechingen
Germany
72379
reinhold.deppisch@gambro.com

Sponsor type
Industry

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Corporate Research

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