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Randomised, long-term administration of pH-neutral peritoneal dialysis solutions containing lactate (BALANCE) or bicarbonate (BICAVERA) in children

Submission date 21/04/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/05/2004	**Overall study status** Completed	
Last Edited 14/07/2014	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
BIOKID

Study objectives
Peritoneal Dialysis (PD) is the preferred dialysis modality in children. Its major drawback is the limited technique survival due to infections and progressive ultrafiltration failure. Conventional PD solutions exert marked acute and chronic toxicity to local tissues. Prolonged exposure is associated with severe histopathological alterations including vasculopathy, neoangiogenesis, submesothelial fibrosis and a gradual loss of the mesothelial cell layer. Recently, more biocompatible PD solutions containing reduced amounts of toxic Glucose Degradation Products (GDPs) and buffered at neutral pH have been introduced into clinical practice. These solutions contain lactate, bicarbonate or a combination of both as buffer substance. Increasing evidence from clinical trials in adults and children suggests that the new PD fluids may allow for better long-term preservation of peritoneal morphology and function. However, the relative importance of the buffer in neutral-pH, low-GDP fluids is still unclear. In vitro, lactate is cytotoxic and vasoactive at the concentrations used in PD fluids. The BIOKID trial is designed to clarify the clinical significance of the buffer choice in biocompatible PD fluids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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

End stage renal disease

Interventions
Two months run-in period: standard PD solution
After randomisation: ten months treatment with pH-neutral double-chambered PD solutions containing either lactate (one group) or bicarbonate (one group)
Examinations: on clinical routine controls: blood tests, peritoneal equilibration tests, intraperitoneal pressure measurement.
If abdominal surgery is indicated: peritoneal biopsy

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Peritoneal dialysis solutions containing lactate (BALANCE) or bicarbonate (BICAVERA)

Primary outcome measure
The primary outcome measure will be the longitudinal change in 4h-D/P creatinine in the sequential PET examinations. Differential changes in this parameter will indicate differences in the development of the peritoneal solute transport status over time.

Secondary outcome measures
Secondary outcome measures will be surrogate parameters of mesothelial cell viability (CA-125), peritoneal neoangiogenesis (VEGF), fibrotic activity (TGF-beta) and local inflammation (Interleukin-6). With the same intention, the evolution of peritoneal histomorphology will be assessed in all patients available for sequential biopsies. Moreover, possible differential effects of lactate and bicarbonate buffer on the control of metabolic acidosis will be assessed by monthly blood gas analyses. Finally, the incidence and clinical course of peritonitis will be recorded as a possible indirect marker of local peritoneal macrophage function.

Overall study start date
01/04/2003

Completion date
30/03/2005

Eligibility

Key inclusion criteria
60 patients (European multicenter trial)
1. One month to 19 years
2. Continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD)
3. Dwell volume 1100 ml/m^2 body surface area
4. Last peritonitis at least three weeks ago
5. Written informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
19 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Reduced efficiency of peritoneal dialysis due to anatomic anomalies or intraperitoneal adhesions
2. Uncontrolled hyperphosphatemia
3. Severe pulmonary, cardiac, hepatic or systemic disease including any kind of malignancy
4. Current or recent (within 30 days) exposure to any investigational drug.

Date of first enrolment
01/04/2003

Date of final enrolment
30/03/2005

Locations

Countries of recruitment
Germany

Study participating centre
University Children's Hospital Heidelberg, Pediatric Nephrology
Heidelberg
Germany
69120

Sponsor information

Organisation

Fresenius Medical Care Deutschland GmbH (Germany)

Sponsor details
Else-Kröner-Strasse 1
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Sponsor type
Industry

ROR
https://ror.org/04sk0bj73

Funder(s)

Funder type
Industry

Funder Name
Fresenius Medical Care (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/10/2004		Yes	No