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Influence of glucose degradation products on residual renal function in peritoneal dialysis (PD) patients

Submission date 02/03/2006	**Recruitment status** No longer recruiting
Registration date 23/03/2006	**Overall study status** Completed
Last Edited 14/10/2009	**Condition category** Urological and Genital Diseases

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

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
4014705 (BfArM)

Study information

Scientific Title

Acronym
DIUREST

Study objectives
Decline of residual renal function in PD patients is slower with the use of PD fluids with low concentration of glucose degradation products compared to standard PD fluids

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bayerische Landesärztekammer, number 98293, 23/02/1999 (primary vote). Also approved by all other local ethics committees.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
End-stage renal disease

Interventions
Conventional PD fluids with high amounts of glucose degradation products versus PD fluids with low amounts of glucose degradation products

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Peritoneal dialysis fluids

Primary outcome measure
Time response of residual renal function

Secondary outcome measures
1. Peritoneal membrane transport parameters
2. CA 125 in effluent as marker for mesothelial cell mass/viability
3. Records of routine blood analyses, hospitalisation, peritonitis episodes, blood pressure

Overall study start date
13/03/1999

Completion date
31/07/2005

Eligibility

Key inclusion criteria
1. End-stage renal disease
2. Treatment with PD
3. Age ≥18 years
4. Residual renal function ≥3 ml/min or creatinine clearance ≥6 ml/min
5. Negative serology for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV)
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Pregnancy and lactation
2. Age >80 years
3. Multiple peritonitis episodes
4. Active malignancy

Date of first enrolment
13/03/1999

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
Germany

Study participating centre
KfH Nierenzentrum
Straubing
Germany
94315

Sponsor information

Organisation
Gambro Corporate Research (Germany)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Corporate Research (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?
Abstract results	476A	01/07/2003		No	No