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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

Contact name
Prof Marianne Haag-Weber

Contact details
KfH Nierenzentrum
St Elisabeth Street 23
Straubing
Germany
94315
marianne.haag-weber@kfh-dialyse.de

Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Controlled, randomised, 2 parallel groups, multicenter

Study type(s)
Treatment

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(s)
Time response of residual renal function

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
Gambro Corporate Research (Germany)

Results and Publications

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