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Effect of low glucose degradation product peritoneal dialysis solution Gambrosol-Trio on residual renal function in patients receiving peritoneal dialysis - a randomized controlled trial

Submission date
18/01/2006

Recruitment status
No longer recruiting

Registration date
02/02/2006

Overall study status
Completed

Last Edited
13/06/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] 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

Protocol serial number
N/A

Study information

Scientific Title
Effect of low glucose degradation product peritoneal dialysis solution Gambrosol-Trio on residual renal function in patients receiving peritoneal dialysis - a randomized controlled trial

Study objectives
That the use of a peritoneal dialysis solution with low concentrations of Glucose Degradation Products (GDP) will reduce the rate of residual renal function decline in patients receiving peritoneal dialysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Scarborough Hospital Ethics Review Board, 27/07/2005, ref: NEPH-27
2. Credit Valley Ethics Review Board, 21/09/2005, ref: KW/EX/05-078
3. The Princess Margaret Hospital Ethics Review Board, 16/06/2005

Study design
Randomized (by the minimization method) controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage renal failure

Interventions
Usual (standard) peritoneal dialysis solution versus peritoneal dialysis solution with low glucose degradation products

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gambrosol-Trio

Primary outcome(s)
Rate of decline of residual renal function

Key secondary outcome(s))
1. Peritoneal ultrafiltration
2. Peritonitis episodes

3. Cardiovascular events (combination of non-fatal myocardial infarction [MI], peripheral vascular disease requiring lower limb amputation, strokes, and deaths due to cardiovascular causes)
4. Peritoneal equilibration test results
5. Peritoneal clearances of urea and creatinine
6. Changes in dialysate CA125 and advanced glycosylated end products

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Age 18 years or above
2. Able to give consent
3. Patient with Peritoneal Dialysis (PD) catheter inserted

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age less than 18
2. Previous hemodialysis
3. Those unlikely to continue peritoneal dialysis for more than six months due to severe comorbid conditions, planned living renal transplantation, or planned transfer to another facility
4. Patients with previous renal transplant
5. Patients starting incremental peritoneal dialysis
6. 24-hour urine volume of less than 100 ml and/or creatinine clearance of less than 1 ml/min
7. Patients with psychiatric diagnoses that might impinge on compliance

Date of first enrolment
01/07/2005

Date of final enrolment
30/06/2009

Locations

Countries of recruitment

Canada

China

Study participating centre
Scarborough General Hospital
Scarborough
Canada
-

Study participating centre
Credit Valley Hospital
Mississaugua
Canada
-

Study participating centre
Princess Margaret Hospital
Hong Kong
China
-

Sponsor information

Organisation
Institute of Kidney Lifescience Technologies (Canada)

ROR
https://ror.org/05vhw2a70

Funder(s)

Funder type
Industry

Funder Name
Gambro, Hong Kong will provide support for measurement of samples and data collection at the Hong Kong site.

Funder Name
The Institute of Kidney Lifescience Technologies, a non-profit organization based in Scarborough, Canada will fund all other aspects of the study.

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?
Results article	results	01/07/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes