

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

Prospectively registered

Protocol

Registration date

02/02/2006

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

13/06/2016

Condition category

Nutritional, Metabolic, Endocrine

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Tam

Contact details

78 Corporate Drive

Unit number 10

Scarborough

Canada

M1H 3G4

+1 (0)416 279 0855

pywtam@yahoo.com

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
Mississauga
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