

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Rate of decline of residual renal function

Secondary outcome measures

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

Overall study start date

01/07/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

98 patients in total from three sites

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)

Sponsor details

78 Corporate Drive
Unit number 10
Scarborough
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M1H 3G4
+1 (0)416 279 0855
pywtam@yahoo.com

Sponsor type

Research organisation

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**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?
Results article	results	01/07/2016		Yes	No