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Evaluating comfort and handling of new patient extension line and bag connector for Peritoneal Dialysis (PD). A short-term, open controlled study.

Submission date 11/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/01/2007	**Overall study status** Completed	
Last Edited 25/01/2007	**Condition category** Urological and Genital Diseases	

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

1443

Study information

Scientific Title

Study objectives
Evaluate patient satisfaction in a first filed utilisation before final desicion on product design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at San Marino University Hospital in Genova , approved on 19/07/2006, ref: 0037753/06

Study design
Open, controlled, single center, comparative prospective pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
ESRD - End Stage Renal Disease

Interventions
Tested products: twist extension line combined with twist female connector on Gambrosol trio.

Reference products: current patient line (PDL 1201-8) and current Gambro CAPD system.
All patients will be treated in a CAPD program exchangning Gambrosol trio GEM 20U03 Ca 2,5 with twist for 3 to 5 exchanges/day following their physician's prescription on glucose concentration to be used. Evaluation on patient satisfaction will be done with a questionnaire at three times: before switch to twist, after two weeks on twist and at four weeks on tested products (end of study).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient satisfaction on handling by comparing current system with new system, twist.

Secondary outcome measures
Collect safety data on new patient line.

Overall study start date
22/01/2007

Completion date
10/03/2007

Eligibility

Key inclusion criteria
1. Patients suffering from chronic renal failure
2. Age 18 years or older
3. Treated in a Continuous Ambulatory Peritoneal Dialysis (CAPD) program with Gambrosol trio (GEM 20U03 Ca 2,5)
4. Treated on CAPD for at least 24 months
5. Signed written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
5

Key exclusion criteria
1. Pregnancy
2. HIV
3. Hepatitis
4. Participation in other studies during the study period if considered to cause interference with either of the studies
5. Treated in a haemodialysis program, patients with diagnosed abdominal pain not related with PD solution
6. Patients on night Automated Peritoneal Dialysis (APD)
7. Peritonitis within one month prior to the study

8. Presence of exit-site/tunnel infection or ongoing peritonitis
9. Impaired and /or disabled patients

Date of first enrolment
22/01/2007

Date of final enrolment
10/03/2007

Locations

Countries of recruitment
Italy

Sweden

Study participating centre
Gambro
Mölndal
Sweden
SE-431 37

Sponsor information

Organisation
Gambro (Sweden)

Sponsor details
Clinical Affairs
Emdalavägen 5
P.O. Box 10101
Lund
Sweden
SE 220 10

Sponsor type
Industry

Website
http://www.gambro.com/start.aspx?id=752

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Gambro (Sweden)

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