

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
Registration date 25/01/2007	Overall study status Completed	☐ Protocol
Last Edited 25/01/2007	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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
1443

Study information

Scientific Title

Study objectives

Evaluate patient satisfaction in a first filed utilisation before final decision 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

Primary study design

Interventional

Study design

Open, controlled, single center, comparative prospective pilot study

Study type(s)

Quality of life

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 exchanging 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(s)

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

Key secondary outcome(s)

Collect safety data on new patient line.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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)

ROR
<https://ror.org/05mw5ed57>

Funder(s)

Funder type
Industry

Funder Name
Gambro (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration