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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.

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

**Protocol serial number**
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

### 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 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(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
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# 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