

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

<b>Submission date</b> 11/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/01/2007	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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 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 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**

Mölnadal

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