Prospective pilot study: evaluation of a new dressing for patients treated in peritoneal dialysis

Submission date	Recruitment status	Prospectively registered
23/08/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/10/2006	Completed	Results
Last Edited	Condition category	Individual participant data
19/09/2007	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1445

Study information

Scientific Title

Study objectives

Evaluation of a new Peritoneal Dialysis (PD) dressing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submitted to CPP Grenoble (reference number: 06-GAMB-1), will receive verdict on 20th September 2006.

Study design

Monocentric, open, comparative study

Primary study design

Observational

Secondary study design

Single-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic renal failure

Interventions

Evaluation of dressing advantages via questionnaires

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Dressing advantages are evaluated via questionnaires, which have to be filled in at specific time schedule. Comfort and safety evaluation will be performed by the patient at the end of each period of product use (end of PD Immo use and end of usual dressing use).

Secondary outcome measures

Handling is also evaluated via the patient questionnaire.

The incidence of Adverse Events (AE) will be followed during the study period.

Overall study start date

25/09/2006

Completion date

25/11/2006

Eligibility

Key inclusion criteria

- 1. Patients with well healed exit site
- 2. Patients treated for at least three months in peritoneal dialysis irrespective of the treatment mode
- 3. Patients with healthy skin judged by investigator
- 4. Patients aged 18 years and older
- 5. Patients having signed a written consent (informed consent) to participate in the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

- 1. Patients treated in hemodialysis
- 2. Patients with diagnosed abdominal pain not related with PD-solution
- 3. Peritonitis within one month prior to the study
- 4. Presence of exit-site, tunnel infection
- 5. Patients with ongoing peritonitis
- 6. Patients participating in other studies during the period of this study
- 7. Patients practising swimming
- 8. Patients under quardianship
- 9. Pregnancy, lactation

Date of first enrolment

25/09/2006

Date of final enrolment

25/11/2006

Locations

Countries of recruitment

France

Study participating centre AGDUC

Grenoble France 38 700

Sponsor information

Organisation

Gambro Industries (France)

Sponsor details

Clinical Affairs Department 61 Avenue Tony Garnier Lyon France 69 007

Sponsor type

Industry

Website

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

ROR

https://ror.org/01mgtdr23

Funder(s)

Funder type

Industry

Funder Name

Gambro Industries (France)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration