

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

Submission date 23/08/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/10/2006	Overall study status Completed	☐ Protocol
Last Edited 19/09/2007	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

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

Handling is also evaluated via the patient questionnaire.

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 guardianship
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)

ROR

<https://ror.org/01mgtdr23>

Funder(s)

Funder type

Industry

Funder Name

Gambro Industries (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration