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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

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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 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)

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 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