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Usability study with the Melio leg bag system

Submission date	Recruitment status	[X] Prospectively registered
23/12/2013	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2014	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2019	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and Study Aims
The purpose of the study is to find out what people who use urine drainage bags with their external sheath drainage system think about a new urine drainage bag product.
The Melio leg bag system has been designed to help users to manage their own leg bags, by reducing the need for carers or family members to assist with emptying the leg bag. It has a pump and long drainage tube to allow users to empty the bag without having to bend down or work a tap. It also has a fill alarm that alerts users when their leg bag needs emptying.
We would like to know whether users find the Melio leg bag system easy to use, and to hear their opinions about the pump and the fill alarm.

Who can participate?
Men over the age of 18 who are long-term users of external sheath drainage systems are invited to take part in the study. All participants will be recruited from users of the Rotherham NHS Trust Continence service.

What does the study involve?
Participants in the study will use the Melio Leg bag for 3 weeks. They will keep a diary whilst they are using the Melio Leg bag and will also complete a questionnaire about their experience of using the Melio Leg bag system.
The diary will have space for participants to write down:
When the fill alarm sounds
When they empty their leg bag
How much urine they empty from their leg bag
Any problems experienced (like leaks or difficulties with the pump)
A continence nurse from the Rotherham NHS Foundation Trust Continence service will visit participants in their home once every week of the study. At these visits they will check for any problems, change the leg bag and collect completed questionnaires and diaries. The visits are likely to last 30 minutes.

What are the possible benefits and risks of participating?
There will be no immediate benefit to patients from taking part in the study. However, it will provide an opportunity to trial a product that may make it easier for them to manage their condition for themselves. If studies show that the Melio bag is beneficial to patients then the overall aim would be to make this product available to patients via the NHS.

The Melio leg bag works in exactly the same way as other drainage bags. The only difference is the way it is emptied. The main risk associated with the study will be patients having difficulty with emptying the Melio Leg bag if they find the pump difficult to use. Patients will be able to contact the continence nurse for assistance if they have any problems whilst using the Melio leg bag. They will also continue to have access to their usual leg bag if they need it.

Where is the study being run from?
Rotherham NHS foundation Trust (UK).

When is study starting and how long is it expected to run for?
The study is expected to begin recruiting in February 2014 and to run until August 2014.

Who is funding the study?
Albert Medical Devices (manufacturer of the Melio leg bag)

Who is the main contact?
Ms Joanne Mangnall, RGN.
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Contact information

Type(s)
Scientific

Contact name
Mrs Joanne Mangnall

Contact details
Rotherham NHS Foundation Trust
Moorgate Road
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S60 2UD

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Usability study with the Melio leg bag system: a non-randomised controlled trial

Study objectives
Users will find the novel features of the Melio leg bag system beneficial and the features will assist users in managing their own urine drainage bag.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application is being made to Yorkshire and Humber Regional Ethics Committee (REC), expected review in January 2014.

Primary study design
Interventional

Study design
Non randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Renal and Urogenital

Interventions
Participants will use the Melio leg bag system for 3 weeks. They will keep a diary of their experience with the bag during this time and complete a questionnaire at the end of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To assess whether end users find the novel features of the Melio leg bag system (a pump for emptying and a fill sensor) to be useful and reliable.

The outcomes will be determined at the end of the study using a combination of a patient questionnaire which will be completed after patients have used the leg bag for three weeks, and diaries which participants will keep throughout the study.

Key secondary outcome(s)
To demonstrate the practicality of the Melio leg bag system in a self-use setting.

Completion date
31/08/2014

Reason abandoned (if study stopped)
Company went into administration

Eligibility

Key inclusion criteria
1. Males over 18 years of age who use external sheath drainage systems and patients of Rotherham NHS Foundation Trust continence service
2. Able to understand the Melio Leg bag system instruction for use and to complete the study

questionnaire (they may have a carer who will assist with these activities)
3. Able to give written informed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Key exclusion criteria
Patients whose need for a catheter is under active review

Date of first enrolment
01/02/2014

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Rotherham NHS Foundation Trust
Rotherham
United Kingdom
S60 2UD

Sponsor information

Organisation
Albert Medical Devices (UK)

Funder(s)

Funder type
Industry

Funder Name
Albert Medical Devices (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration