

Usability study with the Melio leg bag system

Submission date 23/12/2013	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/01/2014	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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.
Joanne.Mangnall@rothgen.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Joanne Mangnall

Contact details
Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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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.

Study design

Non randomized controlled trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

To demonstrate the practicality of the Melio leg bag system in a self-use setting.

Overall study start date

01/02/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

12

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

England

United Kingdom

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

Sponsor information

Organisation
Albert Medical Devices (UK)

Sponsor details
Ic1 Innovation Centre
131 Mount Pleasant
Liverpool
United Kingdom
LV3 1SU

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Albert Medical Devices (UK)

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