User Assessment of the NovaLife Two-Piece Flat Skin Barrier

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The objective of this study is to determine user perception of the 2-piece flat skin barrier compared to the current Dansac flat 2-piece barrier, specifically as it relates to barrier adhesion, barrier tack, comfort, leakage, and ease of barrier…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON40148

Source
ToetsingOnline

Brief title
User Assessment of the NovaLife Two-Piece Flat Skin Barrier

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
colostomy, ileostomy

Research involving
Human

Sponsors and support

Primary sponsor: Dansac Limited/ Hollister Incorporated
Source(s) of monetary or material Support: Dansac Ltd

Intervention

Keyword: colostomy, ileostomy, skin barier, two piece

Outcome measures

Primary outcome

The data will be compiled and reported descriptively. Analysis of the demographic profile and case report forms will be descriptive, with questions reported in tabular format. As this is not a comparative or statistically powered study, no hypothesis tests will be conducted.

Secondary outcome

NA

Study description

Background summary

It is desirable to develop the next generation 2-piece flat skin barrier. The Dansac NovaLife Flat skin barriers in this study are made with a new barrier material called GX+. This material is designed to have increased resistance to erosion to improve wear time for those individuals whose wear time is limited by erosion. The new anges will build on the most successful features from the current Nova Flat product ranges.

Study objective

The objective of this study is to determine user perception of the 2-piece flat skin barrier compared to the current Dansac flat 2-piece barrier, specifically as it relates to barrier adhesion, barrier tack, comfort, leakage, and ease of barrier removal.

Study design

This is a multi-site, unblinded, historically controlled assessment of the new Dansac NovaLife 2 flat 2-piece skin barrier. Study barriers are CE-marked. Subjects are current users of either Dansac flat Nova or NovaLife skin barriers with drainable pouches who have an ileostomy or colostomy. Approximately 30

subjects are enrolled. Subjects are recruited from sites in EU countries. Each subject will be provided 1 box of
5 skin barriers and 1 box of 10 drainable pouches (additional pouches will be provided as needed). Subjects wear the study skin barriers according to their normal habit for 5 consecutive wears. Subjects record wear time and their assessment of relevant characteristics for each skin barrier. In addition, they provide an assessment in comparison to the barrier they normally use (historical control). The study is comprised of 2 visits, an enrollment visit and a completion visit. A phone call is scheduled between the two subject visits. Individual participation is for approximately 10 days based on an average of 2 days wear for each skin barrier (length of study participation may vary depending on typical individual wear time). The Ostomy Comprehensive Health and Life Assessment_ABBR, will be completed at Visit 1.

Intervention

Use of The DansacNovaLife Flat skin barriers GX+.

Study burden and risks

This study is considered of minimal risk in that the anticipated risks of harm are no greater, considering the probability and magnitude, than those ordinarily encountered in the daily routine of the subjects. Subject will not have any benefit from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- is at least 18 years of age.
- has an ileostomy or colostomy
- is at least six weeks postoperative.
- lives and cares for their stoma independently in the community.
- currently uses a Dansac Nova or NovaLife 2-piece flat barrier
- currently uses a drainable pouch.
- is able to wear a 2-piece flat cut-to-fit 55 mm flange.
- has a peristomal skin irritation score of 2 or less.
- is willing to follow the protocol as demonstrated by signing the informed consent and who in the
opinion of the Investigator is qualified to participate.

Exclusion criteria

- has a fistula on or near the stoma.
- has been involved in a study involving stoma care within the last 30 days.
- is pregnant or lactating.
- is undergoing chemotherapy, radiation or steroid therapy.
- has an existing medical condition that would compromise their participation in the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Flat skin barier
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-02-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47398.056.14