Assessment of new enhanced ostomy devices in real-life settings in subjects having an ileostomy

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The aim of the study is to investigate and understand the performance of three new baseplates consisting of a neutralizing layer and one of three adhesives (two new adhesives and one known adhesive) in terms of protecting the skin from damage...

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

Summary

ID

NL-OMON44434

Source
ToetsingOnline

Brief title
CP264

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Artificial opening for faeces; ostomy

Research involving
Human

Sponsors and support

Primary sponsor: Coloplast A/S
Source(s) of monetary or material Support: Coloplast A/S

Intervention

Keyword: Ostomy care, Ostomy product

Outcome measures

Primary outcome

Trans epidermal water loss (TEWL) (30 min) in the inner circle around the stoma. Each TEWL measurement will be repeated three times.

Secondary outcome

Skin measurements and assessments

* TEWL (in the outer circle of the peristomal area) (Three repeated measurements) (30 min)

* pH (0 min and 30 min) in the inner circle around the stoma and outer circle of the peristomal area. Each pH measurement will be repeated three times.

* Potentially thermography pic (0 min and 30 min)

* Hydration (0 min and 30 min) in the inner circle around the stoma and outer circle of the peristomal area. Each hydration measurement will be repeated three times at each point.

* Erythema (0 min and 30 min) in the inner circle around the stoma and outer circle of the peristomal area. Each erythema measurement will be repeated three times at each point.

* Potentially take picture with light box (potentially assess the DET score) (0 min and 30 min)

* Picture of the skin with the Clinical Trial App (at every baseplate change)

* Collection of used baseplates for analysis of the neutralizing layer (from visit 3, 4 and 5)

Leakage assessments

* Leakage area (assessed by picture from app) (at each baseplate change)

* Leakage distance (assessed by picture from app) (at each baseplate change)

* Leakage outside the baseplate (at each baseplate change in clinical trial App)

* Leakage scale questionnaire (at each visit)

Baseline assessments registered at inclusion (visit 0) by the investigator

* Gender

* Age

* Weight

* Height

* Age of stoma (year when created)

* Cause of the stoma (Crohn's disease/Colitis ulcerosa/Cancer/Other)

* Size of the stoma (diameter on widest place and height)

* Current product (brand, product name, item number, size, product type

(1-piece or 2-piece)

* Is the subject used to cut the baseplate? (Yes/No)

* If yes, how much is cut off from the baseplate (template of the baseplate

where the cut is drawn up-on, max cut in mm)

* How often do skin complications occur? (Daily, Every 2-3 days, Once a week,

Once every second week, More rarely)

* Why do you usually change your baseplate? (I change at the same time of the

day, I change when taking a bath/shower, I change when I feel the baseplate

loosens, I change when I feel my skin under the baseplate itches, I change when

I feel my skin under the baseplate is painful, I change when I feel my skin

under the baseplate is burning, I change when I experience leakage, other?)

* Body profile with body check tool

Safety endpoints registered continuously by the investigator

* Concomitant medication

* Adverse events

* Device deficiencies

Endpoints are measured using a clinical eCRF.

Study description

Background summary

Despite development of better ostomy products, people with abdominal stomas (especially an ileostomy) have problems with leakage induced skin disorders which influence their quality of life negatively.To overcome this, Coloplast has developed new ostomy products with a baseplate containing a neutralizing layer that neutralizes output and one of three adhesives (two new adhesives and one known adhesive).

Study objective

The aim of the study is to investigate and understand the performance of three new baseplates consisting of a neutralizing layer and one of three adhesives (two new adhesives and one known adhesive) in terms of protecting the skin from damage induced by output as compared to SenSura Mio® in a real-life setting. The primary objective is to investigate whether a new baseplate with a neutralizing layer can protect the skin from leakage induced skin damage. Secondary objective is to assess the leakage performance of the three new baseplates.

Study design

The investigation is an explorative, partly randomised, open-labelled, controlled, multi-centre cross-over study investigating three ostomy test products. The study set-up is a real-life setting.

Intervention

After informed consent (V0) has been obtained, there will be a screening visit (V1) lasting up to 6 hours.

The study consist of four test periods:
Test period 1: Subjects use SenSura Mio® (1-piece/2-piece Open Flat) for 7 + 3 days
Test period 2: Subjects use Test product A for 14 ±3 days.
Test period 3: Subjects use Test product B or C for 14 ±3 days. *
Test period 4: Subjects use Test product C or B for 14 ±3 days. *

* After all of the subjects have completed test period 2 they will be randomised into one of two possible sequential test periods (test period 3 and 4), where they will wear test product B and C (in randomised order).

Study burden and risks

No other risks are expected than the anticipated adverse events "Peristomal skin irritation (including mechanical trauma)" and "Allergic peristomal skin irritation (dermatitis)" which are well known in connection with the use of ostomy.

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

1. Have given written informed consent
2. Be at least 18 years of age and have full legal capacity
3. Have had their ileostomy for at least 3 months
4 .Must be able to use custom cut product
5. Can use a product with max cut size 45 mm
6. Self-reported problems with leakage (3 x within 14 days)
7. Can handle the Clinical App. and product themselves
8. Users get red skin after exposure to output (screening visit)

Exclusion criteria

1. Are currently receiving or have within the past 2 months received radio-and/or chemotherapy (low doses chemotherapy are allowed for other indications than cancer, e.g. below 15 mg methotrexate for rheumatoid arthritis)
2. Are currently receiving or have within the past month received topical steroid treatment in the peristomal skin area, e.g. lotion or spray. Systemic steroid treatment (e.g. injection, or tablet) are allowed.
3. Are participating in other interventional clinical investigations or have previously participated in this investigation. Participation in other Coloplast in-house clinical investigations are accepted under the circumstances that the subject has paused the activities in the investigation and are otherwise complying with the inclusion and exclusion criteria of this (CP264) protocol.
4. Are currently suffering from peristomal skin problems i.e. bleeding and/or broken skin (assessed by the investigator)
5. Have known hypersensitivity towards any of the products used in the investigation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	CP264 test products - ostomy products
Registration:	No

Ethics review

Approved WMO

Date:	30-11-2017
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	NL63685.056.17