# Investigation of a new stoma product for people with a stoma

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The aim of this investigation is to investigate the performance and safety of a new baseplate comprising a protective layer, which is expected to reduce peristomal skin complications induced by output.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49482

**Source**
ToetsingOnline

**Brief title**
CP288

### Condition

- Other condition

**Synonym**
ileocolostomy, stoma

**Health condition**

ileo- of colostomie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Coloplast A/S
**Source(s) of monetary or material Support:** Coloplast S/A;fabrikant van medische hulpmiddelen

## Intervention

**Keyword:** Colostomy, Ileostomy, Liquid output

## Outcome measures

### Primary outcome

The primary objective is to investigate whether a new baseplate comprising of a

protective layer can reduce peristomal skin complications induced by output.

### Secondary outcome

The secondary objective is to evaluate the psychometric properties of a new

clinical assessment tool for the peristomal skin condition.

# Study description

### Background summary

It is known that a stoma with liquid output can cause skin irritation around the stoma. The non-CE marked investigational product is intended to support collection of output from a stoma and to provide a barrier between peristomal skin and stomal output and it is thought that it causes less skin irritation than the products used so far.

### Study objective

The aim of this investigation is to investigate the performance and safety of a new baseplate comprising a protective layer, which is expected to reduce peristomal skin complications induced by output.

### Study design

This investigation is a randomised, controlled, open-label, comparative, cross-over, multicentre investigation, with two test periods. In total 96

subjects will be included and randomised, and each subject will have three test visits overseen by the Principal Investigator, or delegate. Each subject will be enrolled for 2 × 42±3 days in total for the entire investigation, thus for a maximum of 90 days. The subjects will test the Coloplast investigational product and one of the comparator products in randomised order.

### Intervention

Use of the investigational stoma product compared in a croos over design with another usual stoma product.

### Study burden and risks

The Coloplast investigational product comprises a protecting layer that should help protect the skin from leakage induced skin damage, which could be beneficial for the subjects. The outcome of this investigation will contribute with important information for development of products for subjects with a stoma.
Disadvantages during the investigation could be the extra workload related to completion of questionnaires, visits at site and using the clinical app at each change of product. The subjects are also asked to use a CEmarked competitor product for the comparator test period that may not be their preferred product on the market. The participating subjects will contribute with important information for development of new stoma products, that may have less negative impact on the peristomal skin. Due to the actions taken to mitigate the abovementioned risks, the risks and disadvantages when participating in this clinical investigation are estimated as low. The subject*s health will not benefit directly from this investigation, but they may benefit from the use of the new stoma product through less irritated peristomal skin and improved quality of life in the future.

## 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. Has given written consent to participate by signing the Informed Consent Signature Form
2. Has an ileostomy or colostomy with liquid output (Definition of liquid output: Six-Seven in the Bristol scale (Appendix 5 - Bristol scale)
3. Currently using a flat product
4. Be at least 18 years of age and have full legal capacity
5. Have had their stoma for at least three months (90 days)
6. Can use a product with a max cut size of 40 mm
7. Has experienced leakage* under the baseplate at least three times within the last fourteen days. )*Leakage defined as output seeping under the baseplate (Appendix 6 * Classification of leakage)
8. Has symptoms of peristomal skin complications or has peristomal skin complications defined by at least one of the below
a) Has experienced symptoms of skin complications (itching, burning, pain) within the last fourteen days
b) Has experienced red skin in the inner circle (within three cm from stoma edge) within the last fourteen days
c) Has skin complication (assessed by Principal Investigator, or delegate) in the inner circle (within three cm from stoma edge) of the peristomal area
9. Is able to handle the electronic diary (questionnaire/photo) themselves
10. Is able to handle (apply, remove, cut etc.) the product themselves
11. Is willing to not use barrier film or barrier cream during the investigation
12. Is willing and suitable (determined by Principal Investigator, or delegate) to use a flat custom cut one-piece open or a two-piece open product during the investigation.

13. Is willing to change the product (1pc) or baseplate (2pc) at least every fourth days.

### Exclusion criteria

1. Is currently receiving or have within the past 60 days received radio-and/or chemotherapy; low doses chemotherapy (assessed by Principal Investigator) is allowed for indications other than cancer
2. Is currently receiving or have within the past month received topical steroid treatment in the peristomal skin area, e.g. lotion or spray. Low dose systemic steroid treatment (e.g. inhalation) assessed by the Principal Investigator are allowed. Other systemic steroid treatment (e.g. injection, or tablet) are not allowed.
3. Is breastfeeding
4. Is pregnant (based on pregnancy test - urine)
5. Has known hypersensitivity towards any of the products used in the investigation

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 15 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | CP288 Coloplast |

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|---|---|
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 26-03-2020 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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 | NL71653.068.19 |