ISRCTN23080097 https://doi.org/10.1186/ISRCTN23080097

# Burden of disease in newly operated stoma (an opening to allow faeces to be diverted out of the body) patients

**Submission date**
26/01/2022

**Recruitment status**
No longer recruiting

**Registration date**
04/02/2022

**Overall study status**
Completed

**Last Edited**
24/09/2024

**Condition category**
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
A colostomy is an operation to divert one end of the colon (part of the bowel) through an opening in the belly. The opening is called a stoma. A pouch can be placed over the stoma to collect your poo (stools).
Post-operative high output and peristomal leaking are associated with increased length of stay, readmission, increased healthcare costs, reduced quality of life and skin complications.
The aim of the proposed multi-centred, cross-sectional study is to provide an insight into the baseline burden of disease and health care resource consumption experienced by stoma patients in the first year following surgery.

Who can participate?
Study subjects are adults with a stoma (ileostomy or colostomy) created within time since surgery (0-12 months).

What does the study involve?
During the study, subjects will be invited for a nurse lead interview to collect demographics, healthcare utilisation and assessment of peristomal skin condition. Subjects will subsequently be asked to fill out an online survey within 48 hours of the nurse-led interview. After confirming whether subjects completed the online survey, a reminder will be sent within 72 hours of the nurse-led interview. One week following the initial meeting, the patient will be offered to complete a National Institute for Health Research Patient Research Experience Survey and confirmation of survey receipt will be undertaken.

What are the possible benefits and risks of participating?
This survey-based study presents minimal risk to participants and we have not identified any ethical or legal issues specific to this study. There are no direct benefits associated with participation in this study, other than the information collected in this study will be added to the current knowledge and understanding of patient burden in this disease

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2023

Who is funding the study?
Coloplast UK & Ireland Ltd.

Who is the main contact?
Rachel Ainsworth, gbrah@coloplast.com
Dr Richard Brady, richard.brady32@nhs.net

# Contact information

### Type(s)
Public

### Contact name
Ms Rebecca Mather

### Contact details
Coloplast Ltd
Nene Hall
Peterborough Business Park
Peterborough
United Kingdom
PE2 6FX
+44 (0)1733392000
gbrhc@coloplast.com

### Type(s)
Scientific

### Contact name
Dr Richard Brady

### Contact details
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3HD
+44 1912820488
richard.brady32@nhs.net

### Type(s)
Principal investigator

### Contact name
Dr Richard Brady

### Contact details
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3HD
+44 1912820488
richard.brady32@nhs.net

## Additional identifiers

### Integrated Research Application System (IRAS)
301896

### Central Portfolio Management System (CPMS)
49866

### Protocol serial number
CIPUK01

## Study information

### Scientific Title
CLOUDS-Study: Cross-sectional investigation of burden of disease in newly operated stoma patients

### Acronym
CLOUDS

### Study objectives
There is significant impact from the burden of disease in post-operative stoma patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 22/12/2021, London - Bloomsbury Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048071; bloomsbury.rec@hra.nhs.uk), ref: 21/PR/1574

### Primary study design
Observational

### Study design
Multi-centred cross-sectional investigation

### Study type(s)
Other

## Health condition(s) or problem(s) studied
People with a stoma

## Interventions
The investigation is a cross-sectional, multi-centred study, evaluating the burden of disease by an interview and online questionnaire with an expected duration of 1 week. All visits will be planned to be remote visits, if technically possible. If a remote visit is not possible, a face-to-face meeting will be scheduled, either at subjects' own home or at site.

Once consent has been obtained at an Enrolment/Inclusion Visit (Visit 0), subjects will attend a nurse interview visit (Visit 1) during which the following activities will take place: 1) confirmation of consent; 2) collecting demographic information, healthcare utilisation and peristomal skin condition information; 3) training the subjects on the online survey system and 4) subjects completing baseline questions in the online survey system.

Further surveys will be accessed by the patient in the online system at a time of their convenience and completed over the course of the next 48 hours. Subjects will be called within 72 hours to confirm that surveys have been completed (Visit 2, Survey follow-up).

One week following Visit 1 (unless the patient is planned for a further remote meeting) the patient will be offered to complete a NIHR Patient Research Experience Survey (PRES) and confirmation of survey receipt will be undertaken. If the patient is due to have a further meeting to assist them complete the survey, they will be offered to complete the patient research experience questionnaire at the same time (Visit 3, Participant in Research Experience Survey).

## Intervention Type
Other

## Primary outcome(s)
Patient-reported number of times with stoma effluent leakage outside the baseplate (e.g. onto clothes or bed sheets) within the last 2 weeks, collected using an online survey completed by subjects within 48 hours of nurse-led interview visit (Visit 1).

## Key secondary outcome(s)
1. Leakage-related quality of life & Impact, measured using Ostomy Lead Impact (OLI) questionnaire within 48 hours of nurse-led interview visit (Visit 1)
2. Patient self-management, measured using Patient Activation Measurement (PAM) questionnaire within 48 hours of nurse-led interview visit (Visit 1)
3. Health-related quality of life, measured using EQ-5D-5L questionnaire within 48 hours of nurse-led interview visit (Visit 1)
4. Peristomal skin condition measured using Decision Tree Score based on Ostomy Skin Tool 2.0 at nurse-led interview visit (Visit 1) and online survey within 48 hours of nurse-led interview visit (Visit 1)
5. Mental wellbeing measured using WHO-5 Well-Being Index within 48 hours of nurse-led interview visit (Visit 1)
6. Worry about leakage and actions taken when worrying using online survey within 48 hours of nurse-led interview visit (Visit 1)
7. Odor assessed using online survey within 48 hours of nurse-led interview visit (Visit 1)
8. Changing routine (wear time,reason for change and accessories use) assessed using online survey within 48 hours of nurse-led interview visit (Visit 1)
9. Unplanned changes due to leakage worry assessed using online survey within 48 hours of

nurse-led interview visit (Visit 1)
10. Self-management (feeling of security, confidence in knowing when to change appliance and confidence at night) assessed using online survey within 48 hours of nurse-led interview visit (Visit 1)
11. Impact of leakage on work (sick days), sleep and social activities (2 week recall) assessed using online survey within 48 hours of nurse-led interview visit (Visit 1)
12. Healthcare resource utilisation (2 week recall) assessed at nurse-led interview visit (Visit 1)

### Completion date
16/06/2023

## Eligibility

### Key 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 stoma for less than 12 months
4. Ileo- or colostomists with liquid and/or mushy output (Bristol scale type 5-7)
5. Have intact skin on the peristomal area (assessed by investigator)
6. Have been self-managing stoma appliance for at least 14 days.
7. Must be able to complete the online survey via the EDC system

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
117

### Key exclusion criteria
1. Currently receiving or have within the past month received topical steroid treatment in the peristomal skin area or systemic steroid (tab-let/injection) treatment.
2. Have previously participated in this investiga-tion.
3. Patients with a complicated stoma at baseline (dehiscence/prolapse/hernia)
4. Having more than one abdominal stoma simul-taneously present.
5. Ongoing non-healed abdominal wounds
6. Reoperation / stoma reversal planned prior to completion of first study visit or questionnaire assessments.
7. Limited life expectancy / palliative care patients

8. Stage 4 cancer patients
9. Enrolment into an interventional stoma/stoma device trial within the last 12 months

### Date of first enrolment
15/02/2022

### Date of final enrolment
16/06/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**
Gosforth
Newcastle upon Tyne
Newcastle upon Tyne
United Kingdom
NE3 3HD

### Study participating centre
**Lancashire Teaching Hospitals NHS Foundation Trust**
Avondale Unit
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

### Study participating centre
**James Paget University Hospitals NHS Foundation Trust**
Lowestoft Road
Gorleston-on-Sea
Great Yarmouth
United Kingdom
NR31 6LA

## Sponsor information

**Organisation**
Coloplast UK & Ireland Ltd

# Funder(s)

**Funder type**
Industry

**Funder Name**
Coloplast UK & Ireland Ltd

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository by the study Sponsor

The name of the repository: data will be stored in Coloplast's internal filing system
The type of data stored: all data collected during the study
The process for requesting access (if non-publicly available): N/A; not available to the public
Dates of availability: N/A
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: no identifiable data is stored in the filing system; subjects are identified with a unique study identifier

### IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 02/09/2024 | 02/09/2024 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | version 2.0 | 15/12/2021 | 04/02/2022 | No | Yes |