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Stapled mesh stoma reinforcement technique (SMART) to prevent parastomal herniation

Submission date 04/05/2011	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/05/2011	**Overall study status** Stopped	
Last Edited 04/09/2020	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
A stoma is an opening on the outer surface of the abdomen that is surgically created after removal of part of the bowel or urinary system to divert urine or feces into an external pouch. A parastomal hernia occurs when a weakness in the abdominal wall muscles allows tissue to protrude out, creating a bulge around the stoma. The aim of this study is to find out whether creation of the stoma trephine by a stapling technique together with mesh reinforcement can simplify the reinforcement procedure and reduce the incidence of parastomal herniation compared to standard techniques, whether the stoma is constructed by open or laparoscopic (keyhole) techniques.

Who can participate?
Patients aged 18 and over who require a permanent stoma due to bowel disease

What does the study involve?
Participants are randomly allocated into two groups. One group undergoes standard stoma formation with no reinforcement. The other group receives a stapled trephine with mesh reinforcement. This involves use of a circular stapling device to form and simultaneously reinforce the abdominal wall stoma with mesh. The rate of parastomal herniation is assessed at 24 months after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. The Royal London Hospital (UK)
2. Whipps Cross University Hospital (UK)
3. The Royal Free NHS Foundation Trust (UK)
4. The Royal United Hospital NHS Foundation Trust (UK)
5. Hospital de Sagunto (Spain)
6. Klinikum Chemnitz (Germany)
7. Diakoniekrankenhaus Chemnitzer Land (Germany)
8. Rotkreuzklinikum München (Germany)

When is the study starting and how long is it expected to run for?
April 2011 to September 2020

Who is funding the study?
1. Ileostomy and Internal Pouch Support Group (UK)
2. Enteric Healthcare Technology Co-operative

Who is the main contact?
Prof. Charles Knowles
c.h.knowles@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Charles Knowles

Contact details
National Bowel Research Centre
Blizard Institute of Cell and Molecular Science
Barts and The London School of Medicine and Dentistry
Abernethy Building, 1st Floor
2 Newark Street
Whitechapel
London
United Kingdom
E1 2AT
+44 (0)20 7882 8752
c.h.knowles@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Number 4.0

Study information

Scientific Title
A randomised controlled trial of Stapled Mesh stomA Reinforcement Technique (SMART) versus standard technique to assess effect on parastomal herniation

Acronym

SMART

Study objectives
Creation of the stoma trephine by a stapling technique together with mesh reinforcement can simplify the reinforcement procedure and reduce the incidence of parastomal herniation compared to standard techniques, irrespective whether the stoma is constructed by open or laparoscopic techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London Research Ethics Committee, 19/01/2011, ref: 10/H0706/92

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Parastomal herniation

Interventions
Patients who require permanent colostomy or ileostomy will be randomised into two groups:
1. Standard stoma formation, no reinforcement
2. Stapled trephine with mesh reinforcement. This involves use of a circular stapling device (Compact , Frankenman) to form and simultaneously reinforce the abdominal wall stoma with mesh

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures:
The rate of clinically evident parastomal herniation at 24 months post operatively, as assessed by a local investigator blinded to treatment allocation

Previous primary outcome measures:
1. The rate of clinical herniation evaluated clinically at discharge and at 1, 12, 24 and 60 months post operatively
2. The radiological incidence of herniation detected by computerised tomography (CT) scan at 12, 24 and 60 months after surgery

Secondary outcome measures
Current secondary outcome measures:
1. The rate of clinically evident parastomal herniation evaluated at all other time points (annually up to a maximum of 5 years), as assessed by a local investigator blinded to treatment allocation
2. The rate of herniation as detected by computerised tomography (CT) scan or other radiological examinations of the abdomen, evaluated at 12 and 24 months after surgery
3. Harms including perioperative morbidity (assessed clinically at hospital discharge and at 6 weeks), 30-day mortality and long-term complications
4. The ease of the technique compared with the standard technique, evaluated by bespoke surgeon questionnaire at surgery
5. Quality of life assessed using EuroQol EQ-5D-3L questionnaires preoperatively and at 12 and 24 months post-operatively

Previous secondary outcome measures:
1. Complications associated with the techniques used for the procedures, evaluated at discharge and at 1, 12, 24 and 60 months post operatively
2. The ease of the technique compared with the standard technique
3. Cost/benefit analysis comparing the cost of the stapled reinforcement technique with Vypro® mesh to the standard technique
4. Quality of life assessed using SF36 version 2 and EuroQol EQ-5D questionnaires preoperatively and at 1, 12, 24 and 60 months post-operatively

Overall study start date
02/04/2011

Completion date
30/09/2020

Reason abandoned (if study stopped)
Protocol violations

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/09/2017:
1. Require an elective permanent stoma due to benign or malignant bowel disease
2. Have given written informed consent
3. Be aged 18 and over
4. Able to read and understand English (or language of country of research site)
5. Agree to the randomised procedure
6. If of childbearing potential, must have given a negative pregnancy test
7. Negative Methicillin-resistant Staphylococcus aureus (MRSA) screening test

Previous inclusion criteria:
1. Require an elective permanent stoma due to bowel disease

2. Have given written informed consent
3. Be aged 18 (or be of the age of consent in the country applicable) and over
4. Agree to the randomised procedure
5. If of childbearing potential, must have given a negative pregnancy test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
116

Key exclusion criteria
Current exclusion criteria as of 20/09/2017:
1. Is taking part in another clinical study which directly relates to this study
2. Stoma re-siting
3. Has a history of parastomal herniation.
4. Is suffering from an uncontrolled metabolic or systemic illness (e.g. diabetes or rheumatoid arthritis or any immunological disease) as determined by their responsible physician/surgeon.
5. A diagnosis of mentally limiting conditions such as Alzheimer’s or intellectual disabilty
6. Has clostridium difficile infection resulting in pseudomembraneous colitis
7. Has abdominal wall sepsis

Previous exclusion criteria:
1. Is taking part in another clinical study which directly relates to this study
2. If a patient is taking part in a non-related study, the investigator should discuss with the management team
3. Has a history of parastomal herniation. Such patients will not be randomised but will be offered stoma resiting and mesh reinforcement and followed-up prospectively according to this protocol.
4. Is suffering from an untreated metabolic or systemic illness (e.g. diabetes or rheumatoid arthritis or any immunological disease)
5. A diagnosis of mentally limiting conditions such as Alzheimer's or mental retardation or is unable to understand all study requirements
6. Has Methicillin-resistant Staphylococcus aureus (MRSA) or Clostridium difficile infection
7. Has abdominal wall sepsis
8. Pregnant

Date of first enrolment
02/04/2011

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
England

Germany

Spain

United Kingdom

Study participating centre
Academic Surgical Unit
The Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Whipps Cross University Hospital
Whipps Cross Rd
London
United Kingdom
E11 1NR

Study participating centre
The Royal Free NHS Foundation Trust
Barnet and Chase Farm Hospital
127 The Ridgeway
Enfield
United Kingdom
EN2 8JL

Study participating centre
The Royal United Hospital NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Hospital de Sagunto
Unidad de Coloproctología
Servicio de Cirugía General
Secretaría y Cajal
Sagunto (Valencia)
Spain
s/n 46520

Study participating centre
Klinikum Chemnitz
Altendorf
Flemmingstraße 2
Chemnitz
Germany
09116

Study participating centre
Diakoniekrankenhaus Chemnitzer Land
Limbacher Str. 19
Hartmannsdorf
Germany
09232

Study participating centre
Rotkreuzklinikum München
Nymphenburger Str. 163
München
Germany
80634

Sponsor information

Organisation
Queen Mary, University of London (UK)

Sponsor details
c/o Sally Burtles
Joint Research and Development Office
Queen Mary Innovation Centre
Lower Ground Floor

5 Walden Street
London
England
United Kingdom
E1 2EF
+44 (0)20 7882 7250
sponsorsrep@bartshealth.nhs.uk

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Ileostomy and Internal Pouch Support Group (UK)

Funder Name
Enteric Healthcare Technology Co-operative

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration