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Stoma formation using the sutured trephine annular reinforcement technique

Submission date
24/09/2012

Recruitment status
No longer recruiting

Registration date
15/01/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Parastomal herniation (when the bowel pushes through the muscles surrounding an artificial opening called a stoma and this causes a bulge under the skin) is a common complication following formation of a stoma, occurring in approximately 50% of patients. Although many patients do not suffer from the hernia, approximately 10% require surgical hernia repair, as hernias can cause pain, bag failure, impaired body image and serious/life threatening problems such as bowel obstruction and strangulation of the bowel. Surgical repair of a parastomal hernia is a considerable operation, with its own risks and a high rate of failure (approximately 50%). A technique of using a biological mesh to strengthen the stoma site is currently under investigation and results have shown that reinforcement of the abdominal wall at the stoma site does reduce the incidence of parastomal hernia. This mesh technique is a very costly procedure, so we are aiming to produce the same level of reinforcement of the stoma site using a sutured technique, which will have the same benefits but be less expensive. Comparing both techniques is the aim of this study.

Who can participate?
All patients over the age of 18, who are not pregnant and require a stoma to be formed for bowel disease as an elective procedure. A total of 100 patients are going to be recruited, with 50 undergoing formation of the stoma by the standard technique and the other 50 undergoing formation of the stoma by the Sutured Trephine Annular Reinforcement Technique (START).

What does the study involve?
The patients will be informed about the trial and given a patient information sheet by their lead consultant in outpatients when they are listed for surgery. They will then be seen by a member of the research team prior to surgery, so that any questions can be asked and consent can be gained if the patient agrees to trial entry. The patients are then randomly allocated to one of the two techniques (by use of sealed envelopes which are opened just prior to the formation of the stoma in theatre).
Patients who have their stomas reversed will have the occurrence of any parastomal hernia noted by the consultant surgeon during the reversal procedure. For those patients that do not have their stomas reversed, they will be invited to attend outpatients to have the presence of any parastomal hernia assessed clinically by a member of the research team, who does not which

technique has been used.
All patients will be sent Quality of Life questionnaires at 6 months and 30 months.

What are the possible benefits and risks of participating?
There is a risk that there will be no difference to the patients chances of forming a hernia whatever technique is used to form the stoma. However, there is also a chance that one technique may have a lower hernia rate than the other and this may benefit the patient in terms of stoma related complications and stoma function. The process of placing a reinforcing stitch into the stoma hole will take about 10 minutes, so the patients operation may be very slightly longer. However, this should not represent any significant additional risk to the patients health. Sometimes the stoma hole can be a bit tight and this can cause the stoma not to work properly. Very occasionally this requires a further operation to sort it out. However, this is a risk of standard stoma formation and placing the stitch is unlikely to increase this risk.

Where is the study run from?
This study is taking place in Castle Hill Hospital, Hull (UK).

When is the study starting and how long is it expected to run for?
The study started in September 2012 and is anticipated to run for a total of 30 months after the recruitment of the 100th patient (approximately September 2017).

Who is funding the study?
Spire Hospital and University of Hull (UK). The only additional costs incurred during this study are staffing costs. The study is run by research fellows who are already in funded jobs at the Spire Hospital.

Who is the main contact?
Mr Iain Andrew Hunter
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ASU-IAH-2012.1 START

Study information

Scientific Title
A randomised controlled trial of Sutured Trephine Annular Reinforcement versus standard Technique to assess effect on parastomal herniation

Acronym
START

Study objectives
That stoma formation using the sutured trephine annular reinforcement technique leads to reduced parastomal hernia rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshirew and The Humber - Sheffield, 23/04/2012, ref: 12/YH/0127

Study design
Randomised prospective double-blinded 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 hernias/stoma formation/colorectal surgery

Interventions
Stoma formation via standard trephine formation
Stoma formation via sutured trephine annular reinforment technique

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Parastomal hernia rates at 30 months, or at time of stoma reversal

Secondary outcome measures
1. Stoma related complications requiring hospital admission
2. Changes in quality of life assessments over a 30 month period

Overall study start date
01/09/2012

Completion date
01/03/2015

Eligibility

Key inclusion criteria
Participants must:
1. Require an elective stoma due to bowel disease
2. Have given written informed consent
3. Be aged 18 or 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
100

Key exclusion criteria
Patients must not:
1. Be taking part in another clinical trial which directly correlates to this one
2. Have abdominal wall sepsis

3. Be pregnant
4. Be unable to consent to participation
5. Be undergiong refashioning (but not transposition) of the stoma

Date of first enrolment
01/09/2012

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
R & D Department
Office 6, 2nd floor Daisy building
Castle Hill Hospital
Cottingham
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spire Hospital (UK)

Funder Name
University of Hull (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration