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Assessing the length of Crohn's resection on disease recurrence

Submission date
03/06/2013

Recruitment status
No longer recruiting

Registration date
25/10/2013

Overall study status
Completed

Last Edited
31/07/2020

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Crohn's disease affects any part of the digestive system, most commonly the last part of the small intestine. It usually results in narrowing of the bowel at this point which can prevent food passing through normally. This can lead to abdominal pain, bloating and even vomiting. Whilst Crohn's disease is normally managed with medication, many patients require an operation to remove the affected portion of the bowel. During the operation the affected segment of bowel is removed and the ends of the remaining bowel are joined back together (an anastomosis). Following this, up to 60% of patients develop recurrent symptoms and up to 50% require a further operation. Recurrence of Crohn's disease at the site of the anastomosis can be detected as early as 6 months following surgery. This study is hoping to demonstrate that removing an additional length of small bowel may result in a lower risk of recurrence at the anastomosis, thereby decreasing the need for further surgery in the future.

Who can participate?
Anyone aged 16 or over who is undergoing an operation for Crohn's disease affecting the last part of the small bowel is potentially eligible to enter the study.

What does the study involve?
When patients with Crohn's disease undergo an operation to remove a length of bowel, the bowel is normally divided close (about 2 cm) to the abnormal segment. This is done in the hope of preserving the total length of bowel should future operations become necessary. Sometimes, there is inflammation at these cut ends and this has been associated with an increased risk of recurrence at the anastomosis. Patients who agree to enter the study will be randomly selected to have either an additional 8 cm of bowel removed (extended resection) or have no additional bowel removed (standard resection). At about 6 months after their operation they will undergo colonoscopy. This is to allow us to see the anastomosis visually and take samples from it to see if there are any early signs of disease recurrence.

What are the potential risks or benefits of participating in the trial?
Whilst there may be no immediate benefit to taking part in this study, participation will allow us to find out whether there is any potential benefit to patients with Crohn's disease undergoing an extended resection. This may benefit patients in the future if there is a clear reduction in the

rate of disease recurrence at the site of the surgery. Patients in the study are subjected to exactly the same risks as patients who choose not to participate in the study. These risks are inherent to any operation on the intestines. The risks of the operation will be explained in full at the time of obtaining consent for your operation.

Where is the study run from?
The study is being run from The Churchill Hospital, which is part of Oxford University Hospitals NHS Trust, UK.

When is the study starting and how long is it expected to run for?
The study started in July 2013 and is expected to be completed in six years.

Who is the main contact?
Mr Richard Lovegrove, r.lovegrove@me.com
Mr Bruce George, bruce.george@ouh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Richard Lovegrove

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01876264

Secondary identifying numbers
N/A

Study information

Scientific Title

Crohn's Extent of Resection Trial (CERT): a randomised controlled trial comparing anastomotic disease recurrence following 2-cm versus 10-cm resection margins for patients with ileocolic Crohn's disease

Acronym
CERT

Study objectives
To assess whether undertaking a 10-cm resection margin leads to a reduction in:
1. Endoscopic evidence of disease recurrence at the surgical anastomosis 6 months following ileocolic resection
2. Postoperative disease-modifying medication
3. Symptomatic clinical recurrence
4. Need for reoperative surgery due to recurrence at the surgical anastomosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire B; 14/05/2013; 13/SC/0235
Minor amendments to patient information and consent forms to be made, approval pending.

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Crohn's disease

Interventions
Two arms of the study are:
1. Conventional resection (2-cm margin)
2. Extended resection (10-cm margin)

The intervention group will have an additional 8 cm of distal small bowel resected at the time of ileocolic resection.

Intervention Type
Procedure/Surgery

Primary outcome measure
Endoscopic evidence of disease recurrence at the surgical anastomosis, assessed at 6 months postoperatively

Secondary outcome measures
1. Duration of medication-free interval following resection
2. Duration of symptom-free interval following resection
3. Time to reoperation for anastomotic disease recurrence
4. Extent of plexitis in resected small bowel

Assessed from note review 5 years postoperatively

Overall study start date
01/07/2013

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 16 years or above
3. Patients with ileocolic Crohns disease requiring surgical resection

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
190

Key exclusion criteria
1. Patients unable to give informed consent
2. Patients requiring formation of a stoma at the time of surgical resection
3. Patients having less than 200 cm of small bowel as assessed intraoperatively
4. Simultaneous strictureplasty or small bowel resection
5. Aged <16 or >80 years

Date of first enrolment
01/07/2013

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Colorectal Surgery
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Oxford University Hospitals NHS Trust (UK)

Sponsor details
c/o Mr Bruce George
Churchill Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.ouh.nhs.uk/hospitals/churchill/

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxford University Hospitals NHS Trust (UK) - Surgical Metabolism Fund (0209)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No