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The feasibility of undertaking Appendicectomy to impact upon the Clinical Course of UlceRativE colitis - The ACCURE UK Trial Feasibility Study

Submission date
29/10/2014

Recruitment status
No longer recruiting

Registration date
29/10/2014

Overall study status
Completed

Last Edited
22/01/2018

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a form of inflammatory bowel disease. It is a long-term condition that results in ulcers on the internal surface of the bowel which can bleed and produce pus. Symptoms of the disease include diarrhoea (which may contain blood, mucus and/or pus), abdominal pain and an increase in the need to use the toilet. Patients can go for months with no, or very mild, symptoms (remission) and then suffer a flare up (relapse) where symptoms become much more severe; hospital treatment can become necessary in the worse cases. Most UC patients remain on long-term medication to maintain their lifestyle and prevent flare-ups of disease. Even so, over one third of patients who have had a flare-up of their disease will suffer from another attack within the following twelve months. If this happens, many will need to take more medication, including taking steroids. These flare-ups also effect patients' ability to work and look after children, as well as on their overall quality of life. Doctors are constantly looking for new ways to manage the condition, including developing new drugs to try to prevent or limit disease flare-ups. There is some evidence that the appendix has a role in the regulation of inflammation within the bowel, and that removing the appendix may have a positive impact on how active UC is. This evidence is not yet strong enough to recommend that all patients with UC would benefit from having their appendix removed. We feel that this is an interesting and exciting potential treatment option, and aim to explore it further within this research. Here, we want to find out whether removing the appendix (appendicectomy) can reduce the chances of UC flare-ups. We are going to look at whether it's an attractive treatment to offer to UC sufferers, both from the patients' and the doctors' point of view. If we can successfully recruit patients to this trial, and review them regularly throughout the one year period afterwards, we plan to undertake a follow-on trial in the future to establish exactly how beneficial this treatment is in a larger group of UC patients.

Who can participate?
Adult patients (aged at least 18) that have been diagnosed with UC, currently in remission but have had a disease flare-up within the last 12 months.

What does the study involve?
Firstly, patients undergo a camera examination (endoscopy) of their colon to conform that their UC is currently in remission. Then, having filled in questionnaires on their symptoms and disease activity, they are randomly allocated into one of two groups, the appendicectomy group or the control group. Those in the control group take their standard tablet medication as usual.Those in the appendicectomy group also take their usual medication but they also undergo a appendicectomy. After this stage, regardless of which group patients are in, the follow-up is the same. This involves regular reviews in the outpatient clinic, where the doctor and/or the research team discuss current symptoms and complete further questionnaires. These reviews take place around 6 weeks (appendicectomy group only), 3, 6, 9 and 12 months after entry to the trial. Any patient's medication can be changed or increased during the trial period if felt necessary by the medical team. All medication use is documented during the trial period, and notes made on any other effects of the disease patients suffer, such as time off work or days where patients are unable to function as they would like to. At the end of the trial, a further camera examination of the patient's bowel takes place. As part of the ACCURE-UK trial patients may also be asked to take part in a discussion (research interview) with a researcher from the ACCURE-UK team. These discussions help the team understand what it is like for patients to take part in the study, and help us to make sure that these perspectives influence the design of any follow on trial.

What are the possible benefits and risks of participating?
If allocated to the appendicectomy group and the operation does prove to have an impact on the disease activity in UC, there may be a potential benefit to an individual patient in taking part in terms of reducing the number or severity of disease flare-ups. This may in turn impact upon the future use of medication, number of hospital admissions and the need for major bowel surgery. If allocated to the control group, there is unlikely to be any personal benefit from taking part in the trial, although patients will undergo a period of careful disease medical treatment and monitoring. Some patients will draw satisfaction from the knowledge that their involvement, in either group, will help determine if this new proposed treatment has the potential to benefit all patients affected by UC. However it is important to note that like any surgery there is always the possibility of complications. We have done our best to reduce the chances of these by ensuring that only experienced and specialised colorectal consultant surgeons undertake operations during the trial.

Where is the study run from?
1. Queen Elizabeth Hospital
2. Heartlands Hospital
3. Good Hope Hospital Sutton Coldfield
4. University Hospital of North Tees
5. Leicester General Hospital
6. St Mark's Hospital
7. Walsall Manor Hospital
8. University Hospital of Hartlepool

When is the study starting and how long is it expected to run for?
December 2014 to September 2016

Who is funding the study?
NIHR Research for Patient Benefit (UK)

Who is the main contact?
Dr Laura Magill
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Study website
http://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/coloproctology/accure/index.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17515

Study information

Scientific Title
The feasibility of undertaking Appendicectomy to impact upon the Clinical Course of UlceRativE colitis - The ACCURE UK Trial Feasibility Study: a randomised clinical trial

Acronym
ACCURE-UK Feasibility Study

Study objectives

The ACCURE-UK feasibility study is a 48 patient feasibility with the aim of establishing whether an appendicectomy operation for the treatment of UC is an acceptable option. If appendicectomy is an acceptable treatment option for UC patients and clinicians, a major randomised trial to explore clinical efficacy will be undertaken.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tyne and Wear South Ethics Committee, 24/10/2014, ref. 14/NE/1143

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/coloproctology/accure/investigators/documentation/docs-existingcentres.aspx

Health condition(s) or problem(s) studied
Topic: Surgery, Gastroenterology; Subtopic: Surgery, Gastroenterology; Disease: All Surgery, All Gastroenterology

Interventions
24 patients will be randomised to the control (standard medical therapy), 24 patients will be randomised to the intervention (appendicectomy) plus standard medical therapy.

The intervention is the removal of the appendix as a treatment for ulcerative colitis alongside standard medical therapy.

Follow Up Length: 12 month(s)

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Acceptability of the intervention. Timepoint(s): Baseline, 6 weeks post surgery and 12 months post-randomisation.

Secondary outcome measures

1. Determine the suitability of the QoL outcome measures. Timepoint(s): Analysis of suitability will be after all the collection time-points (>12months)
2. Estimate the morbidity profile of the appendicectomy operation. Timepoint(s): Data will be collected 6 weeks post-surgery
3. Patient-related outcomes e.g. disease-related work absence and loss of earnings. Timepoint (s): 6 weeks post randomisation, 3, 6, 9 & 12 months post randomisation
4. Relapse rate in the control arm. Timepoint(s): This will be collected throughout the trial, at 3, 6, 9 & 12 months;
5. Test the one-year follow-up strategy for the future phase III trial. Timepoint(s): Basline, 6 weeks post surgery, 3, 6, 9 & 12months post randomisation
6. The numbers of eligible, approached and randomised patients. Timepoint(s): During recruitment phase only- 6 months

Overall study start date
20/11/2014

Completion date
29/09/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/01/2018:
The target population for this study is adults with established and recently active UC. The inclusion criteria are as follows:
1. Histologically confirmed UC
2. Disease relapse within 12 months of randomisation
3. In clinical remission at time of randomisation with clinical Mayo score less than 3 and presumptive endoscopic Mayo score of 0 or 1 (to be confirmed later at baseline endoscopy)
4. Aged at least 18
5. Able and willing to give written informed consent

Previous inclusion criteria:
The target population for this study is adults with established and recently active UC. The inclusion criteria are as follows:
1. Histologically confirmed UC
2. Disease relapse within 12 months of randomisation
3. In clinical remission at time of randomisation with clinical Mayo score less than 3 and endoscopic Mayo score of 0 or 1
4. Aged at least 18
5. Able and willing to give written informed consent
6. Male & Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Key exclusion criteria
Current exclusion criteria as of 19/01/2018:
1. Previous appendicectomy
2. Previous major abdominal surgery which would preclude safe laparoscopic appendicectomy
3. Uncertain histological findings and any suspicion of Crohn's disease
4. Infective diarrhoea confirmed by positive stool culture
5. Ongoing active colitis at time of randomisation
6. Patients still on steroid medication for ongoing active or previously active colitis at time of randomisation
7. Patients with significant comorbidity that prevents surgery (eg unstable heart failure)
8. Under the age of 18
9. Unable/unwilling to provide informed consent

Previous exclusion criteria:
1. Previous appendicectomy
2. Previous major abdominal surgery which would preclude safe laparoscopic appendicectomy
3. Uncertain histological findings and any suspicion of Crohn's disease
4. Infective diarrhoea
5. Severe ongoing colitis at time of randomisation
6. Patients with significant comorbidity (eg unstable heart failure)
7. Enrollment in other trial of any novel treatment (including drugs or other interventions) for UC within preceding 6 months
8. Under the age of 18
9. Unable/unwilling to provide informed consent

Date of first enrolment
20/11/2014

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
United Kingdom
B15 2TH

Study participating centre
Heartlands Hospital
United Kingdom
B9 5SS

Study participating centre
Good Hope Hospital
United Kingdom
B75 7RR

Study participating centre
University Hospital of North Tees
United Kingdom
TS19 8PE

Study participating centre
Leicester General Hospital
United Kingdom
LE5 4PW

Study participating centre
St Mark's Hospital
United Kingdom
HA1 3UJ

Study participating centre
Walsall Manor Hospital
United Kingdom
WS2 9PS

Study participating centre
University Hospital of Hartlepool
United Kingdom
TS24 9AH

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-1112-29107

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, submission anticipated March 2018.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	18/03/2015		Yes	No
Results article	qualitative research results	21/08/2017		Yes	No
HRA research summary			28/06/2023	No	No