ISRCTN16900055 https://doi.org/10.1186/ISRCTN16900055

A randomised controlled trial to assess whether the amount of mesentery removed, or the type of bowel join used during surgery for Crohn's disease, can affect the chances of getting further disease

Submission date 16/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/02/2022	**Overall study status** Ongoing	
Last Edited 09/12/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Crohn’s is a disease that makes the bowel red, swollen and painful. It is a lifelong disease. Some people get few flare-ups. Other people may have really bad and long-lasting symptoms. There is no cure for Crohn’s, but drugs can treat the symptoms. If the drugs do not work surgery may be needed. Whilst surgery can also stop symptoms for a long time, the disease can return. Further drugs and even further surgery may be needed. Many surgeons feel that the way the bowel and the tissue containing the blood and other vessels supplying the bowel (the mesentery) is removed and the way the healthy bowel ends are re-joined can affect the success of surgery. Two changes to the way surgeons operate have been proposed. One involves taking out more of the mesentery and the other involves doing another type of bowel join. This is known as the Kono-S join. They are safe but researchers need to test that they are better than the usual method in stopping further disease. In this study the researchers will ask people if they would let them carry out one or both of these methods. They will then see if they have reduced the chances of further disease 1 year later. The type of surgery a person has will be decided by chance.

Who can participate?

Patients who are undergoing surgery (ileocaecal resection) for Crohn's disease where the bowel is re-joined (anastomosis).

What does the study involve?

If a patient is eligible and happy to be part of the study, they will be asked to sign a consent form. They will then complete three questionnaires and be asked some questions about their medical history. On the day of the surgery the surgeon will confirm the patient is eligible and the patient will be allocated to one of the study groups by chance (randomised). The surgeon will then perform the type of surgery as decided by the randomisation. Six weeks after surgery

patients will be asked to complete the questionnaires again during their visit to the hospital (this visit is part of standard care for all patients having this kind of surgery, even if they are not in the trial). After 6 to 12 months patients normally have a colonoscopy as part of the follow-up after the surgery. At this time the participants will be asked to complete the three questionnaires again. The researchers will also look at the participants' medical notes for up to 3 years after the surgery to see if Crohn's disease has come back. At some sites participants will have additional blood and tissue samples taken during their surgery and colonoscopy. These will be analysed to help the researchers understand what might be causing Crohn's disease.

What are the possible benefits and risks of participating?
Taking part in this study will mean no additional appointments at the hospital compared to the number of appointments patients receive normally. The risks associated with the different surgery types are not thought to be any different to usual surgery for Crohn’s disease, and the surgeon will discuss this further with patients as part of standard surgery pre-assessment. Several studies have shown that all the surgical procedures are safe. Complications that are associated with Crohn’s surgery will have been discussed with the patient and include: leak of the join in the bowel, bleeding, bowel blockage (ileus), wound infection, urinary infection, heart events, clots in the leg or lungs, chest infection, hernia, and damage to other parts of the abdomen. Additionally, very rarely patients may have a reaction to the anaesthetic.

Where is the study run from?
The University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
September 2021 to July 2027

Who is funding the study?
National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme (UK)

Who is the main contact?
Steven Brown, steven.brown13@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Jamie Hall

ORCID ID
https://orcid.org/0000-0003-4042-5591

Contact details
Room 2.15, The Innovation Centre
c/o Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA

+44 (0)114 222 2963
jamie.hall@sheffield.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301301

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
52048

Study information

Scientific Title
MEsenteric Excision and Kono-S Anastomosis Trial (MEErKAT)

Acronym
MEErKAT

Study objectives
1. How and why should surgeons consider the mesentery and anastomotic technique in Crohn’s disease?
2. Does Kono-S anastomosis reduce the recurrence of Crohn's disease over standard anastomosis?
3. Does radical mesenteric resection reduce the recurrence of Crohn's disease over standard mesenteric resection?
4. Does a combination of these techniques reduce the recurrence of Crohn's disease over standard mesenteric resection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/04/2022, North East - Tyne & Wear South Research Ethics Committee (+44 (0) 2071048306, +44 (0)22071048285, +44 (0)22071048265; tyneandwearsouth.rec@hra.nhs.uk), REC Ref: 22/NE/0041

Study design
Randomized; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Study type(s)

Treatment

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

Interventions
The trial follows the standard pathway for ileocaecal Crohn’s. Participants are recruited when surgery is deemed appropriate. Potential participants will be discussed at MDT meetings and identified at the time of pre-operative assessment before the day of surgery. Surgeons, research nurses and trainees will also check waiting lists for those listed for ileocaecal resection for primary or recurrent Crohn’s disease. If a patient is interested in taking part, the local research team will review information about their Crohn’s disease from their medical records.

A member of the patient's care team will identify and consent eligible participants. Potential participants will receive an approved Participant Information Sheet (PIS) and be given the opportunity to ask questions from both the surgical and research team. Potential participants will be approached either at their clinic visit prior to surgery or pre-operative assessment. At a pre-operative assessment or on the day of surgery, the surgeon, research nurse or trainee will offer entry into the trial and consent will be obtained. No study-related procedures will occur before the approved consent form is signed, other than the initial case note review for eligibility.

A screening log will be maintained for each hospital site, to document all potential participants screened, whether they were recruited, and any reasons for non-recruitment where this information is available. Screening logs will be requested and reviewed by CTRU on a regular basis.

Baseline Visit
If a patient is happy to proceed, and their surgeon feels the trial is appropriate for them, they will be asked to sign a consent form to join the trial. Following consent, they will then complete separate questionnaires about how they feel (physically and mentally) and about their Crohn’s disease. These are called the IBD-Control, CDAI and EQ-5D questionnaires. These are to help researchers understand a patient's health at the start of the trial and will ask them general questions about their health and specific questions about their Crohn’s disease. The researchers will also take details of the patient's medical history, personal demographics (e.g. gender, ethnicity, etc.) and any medications they are taking.

Day of Surgery
On the patient's day of surgery (which could be the same as the baseline visit), their surgeon will confirm that they still qualify for the trial and they will be randomised to one of the four combinations of surgical techniques (the University of Sheffield provides the randomisation system). The treatment options are as follows:

There are two groups of mesenteric excision and two groups of anastomosis:

Mesenteric Excision Groups
Radical Mesenteric Excision
More mesentery is removed along with the diseased bowel, whilst preserving the main blood supply to the remaining bowel

Close Mesenteric Excision
Minimal mesentery is removed, staying close to the bowel wall.

Anastomosis Groups
Patients randomised to Kono-S
For this anastomosis the resected bowel is stapled perpendicular to the mesentery and the stapled ends sutured together to form the supporting column. The bowel is joined together by hand using stitches and is a different way to join the bowel.

Patients randomised to Standard of Care
Standard care is essentially surgeons' preference of anastomosis. Anastomosis may utilise staples or sutures to join the small bowel and colon after the diseased bowel is removed.

Essentially patients will be randomised onto one of 4 combinations in the ratio 1:1:1:1:
1. Kono-S + radical mesenteric resection
2. Kono-S + close mesenteric resection
3. Standard anastomosis + radical mesenteric resection
4. Standard anastomosis + close mesenteric resection or surgeons' choice

For all cases the mode of access (laparoscopic or open), closure technique and post-operative care are according to usual practice for that participating centre. Whichever surgical technique is selected, it will not have a detrimental effect for patients in the event further surgical procedures are required if the disease does reoccur at the site of resection. The treatment group will not be revealed to the patients (they are blinded), and so are the endoscopists (who perform colonoscopy) at the follow-up visits. It is usual practice for surgeons to take part of the bowel out during the operation and send this for microscopic analysis. The researchers will take small samples of the bowel that has been removed for additional analysis, to review as part of the trial also. They need to see why these new surgical methods may work and clues may be found by looking at those who get further disease after surgery and seeing what part of the join the disease has come back to. They will also leave a small tattoo in the inside of the patient's remaining bowel so that we can identify it when they come back for a telescope assessment of the bowel. This telescopic assessment (colonoscopy) is always carried out 6-12 months after operation, whether patients are in the trial or not. These tattoos are used all the time when doing telescopic camera tests and know they are safe. The tattoo will only be seen if someone looks into the bowel. Patient's care after surgery will be the same as people have after this surgery and who are not in the trial.

It is also useful for our research to take pictures of the bowel that has been removed after surgery has been completed. The researchers will ask patients to consent to having a photo taken of their removed tissue after surgery, directly after the procedure, and will be of the removed tissue pinned onto a specimen board only. They will also take a photograph of the bowel at their follow up colonoscopy to help look at disease recurrence. The anonymised photos will be uploaded to the secure server database at the University of Sheffield that complies with the Data Protection Act (2018) and uses industry-standard techniques to provide security. The photos will be used for the central assessment of each surgery, to ensure consistency in surgical technique across the trial and disease assessment.

Week 6
After the patient has recovered from their surgery and has been discharged from hospital, they will come back to clinic at around 6 weeks after the procedure. This is in line with standard of care after this type of surgery. At this visit, the researchers will check how they are and they will also be asked to complete the IBD-Control, CDAI and EQ-5D questionnaires again.

Follow Up
As mentioned earlier, it is usual after this operation to have a colonoscopy about 6 to 12 months

after surgery. This looks at the bowel join (including the tattoo inked at surgery). It is also usual to have some small biopsies taken at this time. The research team will also ask patients to complete the three questionnaires - IBD-Control, CDAI and EQ-5D – and ask what medications they are taking and whether they have had any side effects since their operation. Finally, they will also look at patients' medical notes up to three years after their surgery to see if any recurrence has occurred. The trial does not involve any other visits or treatments above normal routine care.

Mechanistic Sub-Study
The researchers are running a small optional sub-study for a group of around 140 patients to assess what might be causing recurrent Crohn's disease. It is referred to as a 'mechanistic sub-study' as it is looking at the mechanisms (e.g. types of tissue, immune cells, etc.) of why Crohn's disease may reoccur in more detail, along with data from the main trial. If a patient agrees to take part in this part of the study, an additional set of blood and tissue samples will be taken at their surgery and colonoscopy follow up:

Immediately before surgery:
Blood samples (5-10ml, around 2 teaspoons)

At operation:
Extra tissue samples 5-10mm in size will be taken from the part of the bowel and mesentery that has been removed.

At colonoscopy:
2-4 tiny biopsies will be taken from the lining of the small bowel

Blood samples (5-10 ml, around two teaspoons):
No extra visits are required, as the samples will be taken at the existing trial visits. Consenting to this part of the trial is entirely optional for patients and will only be run at specific centres.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to endoscopic recurrence of disease using the Modified Rutgeerts score (≥i2) from the date of randomisation after 6-12 months to a maximum of 3 years follow-up

Key secondary outcome(s))
1. Incidence of severe endoscopic recurrence measured using the Modified Rutgeerts score ≥i3 after 6-12 months to a maximum of 3 years follow-up
2. Clinician and patient-reported symptomatic recurrence at 6-12 months and at the end of the trial. The definition of symptomatic recurrence will be:
2.1. Self-reported recurrence in combination with endoscopically confirmed recurrence; OR
2.2. Surgical re-intervention in combination with histological confirmation of recurrence; OR
2.3. Change of medical strategy for reasons other than safety/tolerability; OR
2.4. IBD Control >13; OR, Crohn's Disease Activity Index (CDAI) >220
3. Quality of life measured using EQ-5D-5L at 6-12 months after surgery
4. Time to endoscopic recurrence for all groups measured using Modified Rutgeerts score (≥i2) for at least 6 months and up to 3 years after surgery
5. Surgical recurrence measured using clinician and patient report at a minimum of 6 months and a maximum of 3 years

6. Radiological and surgical anastomotic leak (following surgery) as defined by the latest consensus; other complications for each intervention (surgical complications may include, but are not limited to haemorrhage; ileus/bowel obstruction; wound infection; urinary tract infection; cardiac events; pulmonary embolism [PE]/deep vein thrombosis [DVT]; and respiratory insufficiency/pneumonia. Late postoperative complications may include: trocar-site and incisional hernia; ureteral stenosis [retroperitoneal fibrosis]) recorded at surgery, following surgery and within at least 6 months and a maximum of 3 years following surgery
7. Mesenteric disease severity measured using the mesenteric disease activity index at surgery

Completion date
30/07/2027

Eligibility

Key inclusion criteria
People aged over 18 years undergoing ileocaecal resection for primary/recurrent Crohn's disease where an anastomosis is carried out

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
999 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participant exclusion criteria as of 10/11/2023:
1. Patients with markedly extensive inflammation affecting the vascular root of the mesentery seen on imaging or at operation
2. Patients undergoing stoma formation proximal to the anastomosis
3. Patients who have a contraindication to subsequent colonoscopy
4. Patients unable to give full informed consent
5. Patients who are pregnant (as ascertained by standard pregnancy tests undertaken at preoperative visits as per standard clinical care)
6. Patients who, in the opinion of the principal investigator, do not meet the criteria for relevant surgery

Previous participant exclusion criteria:
1. Patients with markedly extensive inflammation affecting the vascular root of the mesentery seen on imaging or at operation
2. Patients undergoing stoma formation
3. Patients who have a contraindication to subsequent colonoscopy
4. Patients unable to give full informed consent
5. Patients who are pregnant (as ascertained by standard pregnancy tests undertaken at preoperative visits as per standard clinical care)
6. Patients who, in the opinion of the principal investigator, do not meet the criteria for relevant surgery

Date of first enrolment
02/05/2022

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
England
S5 7AU

Study participating centre

Norfolk & Norwich University Hospital
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Guys Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
England
OX3 7LE

Study participating centre
University Hospital (coventry)
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Solihull Hospital
Lode Lane
Solihull

England
B91 2JL

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
England
TR1 3LJ

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
England
DY1 2HQ

Study participating centre
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
England
BS2 8HW

Study participating centre
Central Middlesex Hospital
Acton Lane
London
England
NW10 7NS

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
England
NN16 8UZ

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Huddersfield Royal Infirmary
Acre Street
Huddersfield
England
HD3 3EA

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
England
SW10 9NH

Study participating centre
Bolton Royal Hospital
Minerva Road
Farnworth
Bolton
England
BL4 0JR

Study participating centre
Queen's Hospital Burton
Belvedere Road

Burton on Trent
England
DE13 0RB

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Sandwell District General Hospital
Lyndon
West Bromwich
England
B71 4HJ

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road

Sheffield
England
S5 7AU

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
Scotland
PA2 9PN

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR

https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131988

Results and Publications

Individual participant data (IPD) sharing plan
The results will be published on a freely accessible database within 1 year of completion of the trial.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	28/06/2023	19/01/2024	No	No
Statistical Analysis Plan	version 1.0	24/07/2023	19/01/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes