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A trial to determine if a special liquid diet (exclusive enteral nutrition) before Crohn's disease surgery improves recovery

Submission date 25/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 10/08/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/04/2026	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Crohn’s disease is a lifelong inflammatory illness that causes people to have severe stomach pains, chronic diarrhoea, and suffer weight loss. There is no cure. Crohn’s disease causes inflammation, ulceration, bleeding and narrowing of the digestive system. People can have periods of good health (remission) and times when symptoms are more active (flare-ups or relapses). Medications can help keep it in remission, however, one-third of people will need surgery to remove/repair part of their diseased gut at some stage.

Previous studies suggest that a special liquid diet might help improve recovery from surgery. This diet is called exclusive enteral nutrition (EEN) because it is the only form of food taken for a period of time. In active Crohn’s disease, this special liquid diet can improve symptoms, reduce inflammation and heal the gut better than steroids. EEN is not offered routinely to patients at the moment because we don't have any evidence-based research.

This study aims to find out whether 6 weeks of EEN diet pre-surgery might help participants recover quicker and make the surgery safer with less chance of complications compared to a usual diet pre-surgery.

Who can participate?

Patients aged 16 years and over from across the UK due to have surgery for Crohn’s disease

What does the study involve?

Participants are randomly allocated to a minimum of 6 weeks of EEN pre-operatively or the usual diet. All patients will undergo surgery and be followed up for 1 year with information about disease activity, medication use, health-related quality of life and health resource usage is obtained. An embedded study will explore patients' and healthcare professionals' views and experiences of all aspects of the study. There is an optional sub-study which involves a more detailed assessment of outcomes related to early/late surgery and dietary aspects in terms of nutrient intake, dietary habits and food-related quality-of-life. The follow-up schedule is designed to collect data only at time points comparable to common clinical practice to reduce patient burden and the need to attend additional hospital appointments.

What are the possible benefits and risks of participating?
If the liquid diet can be shown to improve symptoms, widespread uptake is anticipated. Participants in both groups will be undergoing elective surgery as part of their standard medical care. The trial intervention is purely nutritional, with the main risk relating to poor tolerance of the EEN. This could mean that some patients in the EEN arm may not meet their nutritional requirements. However, this risk will be mitigated by having close dietitian follow-up and by not mandating a particular type of EEN to be used within the study. Hospitals have more than one type of EEN available. Participants will be allowed to choose from the EEN available at each site until they can find one that they can tolerate. They can also use a variety of EEN supplements to minimise taste fatigue. Participants will be made aware of the risks and benefits during the consent process and written information will be provided in the patient Information Sheet. The participants' GPs will also be informed that their patients are participating in a clinical trial and of the allocated treatment.

Where is the study run from?
Birmingham Clinical Trials Unit based at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
May 2022 to April 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
325763

Central Portfolio Management System (CPMS)
56722

Protocol serial number
2.0

Study information

Scientific Title
Optimisation before Crohn's surgery using exclusive enteral nutrition

Acronym
OCEaN

Study objectives
To determine if pre-operative exclusive enteral nutrition (EEN) is more clinically and cost-effective compared with usual diet in patients undergoing surgery for Crohn's disease (CD).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/07/2023, London City & East REC (Research Ethics Committee Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048171; cityandeast.rec@hra.nhs.uk), ref: 23/LO/0513

Primary study design
Interventional

Study design
Multi-centre two-arm parallel-group open-label pragmatic randomized controlled trial with a mixed methods internal pilot

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Planned surgery for small bowel and/or colonic Crohn's disease (primary or repeat surgery)

Interventions
The intervention is a minimum of 6 weeks of EEN pre-operatively. The control group is the usual diet.

Following randomisation into the trial, participants will be reviewed by the local dietitian, and their feed will be prescribed. The type of EEN formula prescribed to each participant will be decided by dietitian preference and/or local availability. If participants cannot tolerate the first feed prescribed, an alternate EEN formula can be used, or participants can use a variety of EEN feeds to reduce taste fatigue. Feeds may be concentrated to reduce the volume of feeds consumed. If tolerance remains poor, nasogastric feeding can be offered.

The start date of EEN will be agreed between the dietitian and the participant. An online support tool (FutureLearn Ltd), developed with the patient panel and Crohn's and Colitis UK, will provide information, peer support and assistance to participants randomised to EEN, which will also help facilitate adherence to an EEN diet. The OCEaN trial team have developed some EEN diet patient support sheets to help support patients on the liquid diet, as well as standardise the delivery of the EEN across the sites as much as possible. EEN is often started by the hospital dietitian and then continued by either the hospital or provision is transferred to the community dietitians and/or the GP. This pathway is likely to vary between sites, and so will be directed by local practice and local resources.

Intervention Type
Supplement

Primary outcome(s)
Dual primary outcomes at 6 weeks post-surgery:
1. Crohn's Life Impact Questionnaire (CLIQ; a CD-specific patient reported outcome assessing QoL)
2. Post-surgery complications using the Comprehensive Complication Index (CCI)
If we demonstrate benefit for EEN on either of the primary outcomes this establishes effectiveness

Key secondary outcome(s)
Patient reported:
1. QoL over time using the CLIQ which will be collected post-surgery, fortnightly until 12 weeks post-surgery and then monthly up to 24 weeks post-surgery
2. Post-surgery recovery using the Surgical Quality of Recovery-15 (QoR-15) on day 3 post-surgery (or pre-discharge if discharged before day 3). The QoR-15 is a short form version of the QoR-40 and consists of 15 items each with a numerical rating score of 0-10. The total score therefore ranges from 0 to 150, with higher scores indicating better quality of recovery.

Clinical:
3. Length of post-operative hospital stay (measured in nights in hospital)
4. Length of bowel resected (in centimetres measured along anti-mesenteric border) at time of surgery before being put in formalin
5. Number of anastomoses formed at surgery as documented in the operation notes or from discussion with the operating surgeon
6. Number of participants requiring stoma formation either at index operation or within 30 days of surgery due to re-operation
7. Number of participants who develop an anastomotic leak (either radiological concern or confirmed at reoperation) within 30 days of surgery
8. Number of participants re-admitted within 30 days of date of discharge
9. Number of participants requiring re-operation within 30 days of surgery
10. Number of participants who develop enterocutaneous fistulae within 90 days of surgery. This is defined as any new fistula tract from any point in the gastrointestinal tract opening on to skin at any site from day of surgery to 90 days later. Enterocutaneous fistula diagnosis can be confirmed following clinical assessment. Radiological confirmation is not required.
11. Number of participants who develop clinical recurrence of their CD at 24 and 52 weeks post-surgery as assessed by the Crohn's Disease Activity Index (CDAI)
12. Number of participants who develop endoscopic disease recurrence assessed endoscopically on colonoscopy performed between 24 and 52 weeks post-surgery as part of standard of care. (66, 67) Modified Rutgeert's score should be used to grade the severity of recurrence. (67) If

endoscopy is not performed but patient has cross sectional imaging (e.g. Magnetic resonance imaging (MRI), Computerised Tomography (CT) or ultrasound) as part of standard of care (routine assessments), the presence or absence of disease recurrence on imaging can be used as an alternative.
13. Number of participants on steroids at baseline who were able to wean off steroids prior to surgery. Steroid usage and dosage (including prednisolone (oral/rectal), Budesonide (oral /rectal), Hydrocortisone (intravenous/oral)) will be recorded at baseline and on day of surgery to determine change in use or dose. Inhaled or topical steroid use is not relevant to this trial.
14. Safety assessed through adverse event and serious adverse event reporting
15. Number of participants whose planned surgery did not proceed due to clinical improvement. If planned surgery is cancelled by the local team because clinical improvement deems it no longer necessary, these participants will continue to follow the trial protocol (e.g., follow-up assessments etc.)
16. Number of participants who required expedited or emergency surgery. This refers to participants whose elective/planned CD surgery date is brought forward due to clinical deterioration.

Economic outcomes:
17. The EuroQoL-5D-5 Level (EQ-5D-5L) questionnaire and an incremental cost-utility analysis will determine the cost per quality-adjusted life year (QALY) gained over the 52 weeks post-surgery. The EQ-5D-5L will be collected pre-operatively, and then at 6 weeks post-operatively, and then also at 24 and 52 weeks post operatively.

Qualitative outcomes:
18. Interviews will be undertaken with participants randomised to both trial groups, and also with staff involved in the trial. This research aims to provide in-depth qualitative data concerning the acceptability and experience of EEN as a pre-surgical intervention.

Exploratory outcomes:
19. Change in the Harvey-Bradshaw Index (HBI) and CLIQ between baseline and pre-operatively to determine if EEN improves HBI and CLIQ.
20. To determine if baseline microbiome compositional and metabolomic signatures, and changes after 6-weeks of EEN, can predict primary and secondary trial outcomes including post-surgical complications and likelihood of disease recurrence at follow-up. The samples are being collected as part of the main trial in order to measure faecal calprotectin. Further analysis will be performed and funded separately by UoG.

COAST sub-study outcomes:
21. COAST will analyse the subset of participants who are having surgery for terminal ileal CD to determine the impact of surgical timing on QoL and cost.

Microbiome analysis outcomes:
22. As an exploratory trial outcome, we will study if baseline microbiome compositional and metabolomic signatures, and changes after 6-weeks of EEN, can predict primary and secondary trial outcomes including post-surgical complications and likelihood of disease recurrence at follow-up.

Completion date
01/04/2026

Eligibility

Key inclusion criteria
1. Any patient undergoing planned surgery for small bowel and/or colonic CD (primary or repeat surgery)
2. Age ≥16 years
3. Willingness to go on EEN for the duration of the intervention period (minimum of 6 weeks)
4. Capacity to give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Surgery for peri-anal CD, ulcerative colitis, or inflammatory bowel disease unclassified (IBDU)
2. Patients who require parenteral nutrition in the 6 weeks prior to surgery
3. Inability to comply with the trial schedule and follow up

Date of first enrolment
11/04/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Dorset County Hospital
Williams Avenue
DORCHESTER
England
DT1 2JY

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
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England
DL3 6HX

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
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London
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W2 1BL

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
England
TS24 9AH

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University College London Hospitals NHS Foundation Trust
250 Euston Road
London
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NW1 2PG

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Liverpool University Hospitals NHS Foundation Trust
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England
L7 8XP

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Maidstone and Turnbridge Wells NHS Trust
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ME16 9QQ

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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England
NE7 7DN

Study participating centre
Lewisham and Greenwich NHS Trust
Lewisham High Street
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SE13 6LH

Study participating centre
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TR1 3LJ

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Dartford and Gravesham NHS Trust
Darenth Wood Road
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DA2 8DA

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Croydon Health Services NHS Trust
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St Marks Bowel Cancer Screening Centre
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HA1 3UJ

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King's College Hospital NHS Foundation Trust
Denmark Hill
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SE5 9RS

Study participating centre
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S5 7AU

Study participating centre
Manchester University NHS Foundation Trust
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Leeds Teaching Hospitals NHS Trust
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LS9 7TF

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University Hospitals Plymouth NHS Trust
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PL6 8DH

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The Royal Wolverhampton NHS Trust
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The Dudley Group NHS Foundation Trust
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DY1 2HQ

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RH1 5RH

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Cambridge University Hospitals NHS Foundation Trust
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University Hospitals Birmingham NHS Foundation Trust
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University Hospitals of Leicester NHS Trust
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Northwick Park Hospital
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HA1 3UJ

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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the BCTU Data Sharing Committee.
ocean@trials.bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/04/2026	23/04/2026	Yes	No

HRA research summary		20/09/2023	No	No
Study website	11/11/2025	11/11/2025	No	Yes