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Better understanding of the causes, how best to treat and how to develop new medications for Crohn's and colitis by studying human cells and gut microbes

Submission date
27/01/2025

Recruitment status
Recruiting

Registration date
01/04/2025

Overall study status
Ongoing

Last Edited
01/04/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
The number of new people being diagnosed with Crohn's and colitis is rising each year. Symptoms can be very different from one person to the next - some people will have inflammation which gets worse over time whereas in others the inflammation is easily treated. Unfortunately, we don't know why Crohn's and colitis starts or what controls this behaviour over time. Our team of researchers think that studying the behaviour of human cells in the blood and gut, studying gut microbes (bacteria, viruses and fungi) and other factors at the time of Crohn's and colitis diagnosis and repeatedly over the first 2 years after diagnosis may help to better understand why everyone's experience is so different and what makes us so individual. We hope that doing this will allow us to work out which people most need treatment early after diagnosis, and which treatment to choose. We hope this study in the future will help to better predict how Crohn's and colitis may behave for different people, make new treatments for Crohn's and colitis and support people to make personalised choices about their care with their doctors and IBD nurses.
The study aim is to recruit 1,000 IBD participants and up to 1,000 non-IBD control participants and collect health data and biosamples for research. Samples taken will be analysed for human and microbe cells, genetic material and metabolic products that may determine an individual patient's pattern of disease and guide the most effective treatment options.

Who can participate?
Adults aged 16 years and over with a suspected diagnosis of IBD

What does the study involve?
This study involves collecting information and samples from people who have symptoms that mean they might have Crohn's or Colitis:
Upfront tests
1. We will collect a stool sample and blood sample and you will complete some questionnaires about your lifestyle, diet and the impact of your symptoms.

2. We will take additional biopsy samples during your diagnostic colonoscopy (an exploration of the bowel with a flexible camera) that you will have as part of your standard hospital care.

If you are not diagnosed with Crohn's or Colitis
1. No further research visits are needed, but we would like to access your medical records later on to collect information on any Crohn's or Colitis-related symptoms or conditions you may subsequently develop.
2. You will continue to be seen by the hospital for any NHS tests or follow-ups you need.

If you are diagnosed with Crohn's or Colitis
1. We will collect stool samples and blood samples every three months for the first year and you will be given health questionnaires to complete.
2. We will repeat the above every 6 months for the second year.
3. You will have a follow-up colonoscopy after 1 year to check on the health of your bowel.

Taking part in the study will not impact the treatment you receive, however, if you are diagnosed with Crohn's or Colitis you may have access to more frequent check-ups and enhanced access to your dedicated Crohn's and Colitis team than if you didn't take part.

What are the possible benefits and risks of participating?
The potential benefits are regular face-to-face reviews with experts highly experienced in the management of Crohn's and Colitis and a faster diagnosis than in standard NHS practice. These study reviews can provide patients with access to support, knowledge and expertise at regular time points following diagnosis. In addition, if diagnosed with Crohn's or Colitis, the implementation of regular tests which form part of the research study will provide information about how patients are responding to any treatments and potentially identify problems early. This includes a colonoscopy assessment 12 months after diagnosis to check on the health of the intestine, to check the response to treatment and to decide if any further changes to treatment should be made. The longer-term benefits of the Open-IBD study are for the wider Crohn's and Colitis community rather than individual patients. This study will improve the understanding of the links between gut microbes, genes, diet and Crohn's and Colitis. It also aims to identify how these factors influence an individual's response to treatment. This study seeks to identify, at the time of diagnosis, which patients are likely to develop more complicated forms of the disease and to provide them with the most effective treatments early on.
The study involves the collection of blood and tissue samples. As with any medical procedure these carry small risks, but we minimise these by having them carried out by qualified and trained hospital staff. These procedures are standard practice whether patients join the study or not. Blood sampling can cause discomfort and may cause a small bruise. Tissue samples (biopsies) are taken as part of your routine clinical care and at the same time, some additional samples would be taken and used for the study. When a biopsy is taken, there is a small risk of bleeding (1 in 150 chance) and there is a very small risk that the procedure could create a hole in the bowel (perforation) (1 in 1500 chance).

Where is the study run from?
Newcastle Clinical Trials Unit (Newcastle University) (UK)

When is the study starting and how long is it expected to run for?
January 2024 to July 2029

Who is funding the study?
EMBL Enterprise Management Technology Transfer GmbH (Germany)

Who is the main contact?
Prof. Chris Lamb, christopher.lamb@newcastle.ac.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
345768

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 65251, Grant Codes: 220540/Z/20/A

Study information

Scientific Title
Open-IBD: a longitudinal multi-omics inception cohort in inflammatory bowel disease

Acronym
Open-IBD

Study objectives
Study hypothesis not available, however, the overarching objective for the study is to recruit 1,000 IBD participants and up to 1,000 non-IBD control participants with the collection of clinical metadata (including disease activity and quality of life measures and environmental exposures),

and biosamples for research. Samples taken will be analysed for human and microbe cells, genetic material and metabolic products that may determine an individual patient’s pattern of disease and guide the most effective treatment options.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2024, Wales Research Ethics Committee 1 Cardiff (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2922 940912, +44 (0)292 2940931; Wales.REC1@wales.nhs.uk), ref: 24/WA/0338

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory bowel disease

Interventions
Open-IBD is a multi-centre, prospective, observational, inception cohort study of inflammatory bowel disease (comprising Crohn’s disease and ulcerative colitis) with approximately seven UK sites.

The overall recruitment sample will comprise of two cohorts:
1. ‘IBD cohort’ = subjects with inflammatory bowel disease; anticipated 50:50 split between ulcerative colitis/inflammatory bowel disease unclassified (IBD-U) and Crohn’s disease.
2. ‘Non-IBD cohort’ = additional subjects referred to hospital with suspected IBD where investigations do not confirm IBD. Anticipated diagnoses in this group include but are not limited to microscopic colitis, coeliac disease, infective colitis, diverticulitis, colorectal cancer and irritable bowel syndrome.

Patients will be identified by the gastroenterology teams and screened against the study eligibility criteria using the patient's medical records. Eligible patients will have the study explained to them by a member of the study team and be given the Participant Information Sheet for further information.

Informed, written consent will be sought prior to any baseline data data collection. Participants will provide informed consent electronically, using an approach developed and used successfully for other studies. If preferred, participants can also complete informed consent and questionnaires in paper form.

Some study assessments will be completed remotely, at participants' homes and some during hospital visits. Each participant will therefore be provided with access to an online database to complete questionnaires and track samples, the study database.

All participants will be enrolled for approximately 48 months, with assessments done at baseline (prior to starting treatment). Once the diagnosis has been established participants will be allocated to either the ‘IBD cohort’ or the ‘Non-IBD cohort’.

Participants allocated to the 'IBD cohort' will then have hospital visits at months 3, 6, 9, 12, 18 and 24. After month 24 visit there will not be any other hospital visits as part of this study. At months 36 and 48 research staff will collect data from participants' medical records only.

Participants allocated to the 'non-IBD cohort' will not have any other hospital visits, following their baseline visit. The local research team will only collect data from their medical records at months 24, 36 and 48.

The OPEN-IBD research team at site will be available to support and help with any questions or concerns about the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Recruitment of 2000 patients within 4 years: The number of recruited participants will be reported through the recruitment report generated at the end of the recruitment period.

Key secondary outcome(s))
1. Clinical disease activity measured using the patient-reported outcome (PRO)-2 at baseline and months 3, 6, 9, 12, 18 and 24
2. Endoscopic disease activity measured using the ulcerative colitis endoscopic index of severity (UCEIS) or the Simple Endoscopic Score for Crohn’s Disease (SES-CD) at baseline and month 12
3. Patient report measure of disease control measured using IBD Control at baseline and months 3, 6, 9, 12, 18 and 24

Completion date
31/07/2029

Eligibility

Key inclusion criteria
All patients must fulfil the following criteria to be enrolled in the study.
1. Suspected diagnosis of IBD i.e. referred to/presenting within hospital as part of the IBD diagnosis pathway, for example:
1.1. People being referred from primary care to secondary care with gastrointestinal symptoms and/or tests available in primary care suggestive of gastrointestinal pathology that may be due to inflammatory bowel disease e.g. a raised faecal calprotectin or faecal immunochemical test (FIT).
1.2. People being referred between or within or between secondary care specialties with test results or symptoms suggestive of gastrointestinal pathology that may be due to inflammatory bowel disease.
1.3. People identified in secondary care services to have radiological features of inflammatory bowel disease but where diagnostic lower gastrointestinal endoscopy has yet to happen or is

not planned e.g. ileitis or perianal sepsis identified on cross-sectional imaging.
1.4. Patients presenting/admitted to hospital with suspected or confirmed new onset inflammatory bowel disease.
2. Adults aged 16 years and over
3. Willing and able to provide informed consent
4. Willing to undertake the following study procedures:
4.1. Completion of questionnaires
4.2. Collection of stool specimens at home
4.3. Provision of blood and biopsy samples during hospital visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
The following exclusion criteria apply:
1. Potential participants should not be currently receiving treatment with oral corticosteroids or an advanced therapy (biologic, JAKi or S1P receptor modulator) if commenced as treatment for suspected IBD.
1.1. The exception are patients admitted to hospital due to suspected new onset inflammatory bowel disease consistent with acute severe colitis (ASC) who have received 7 days or less of oral or intravenous corticosteroids or advanced IBD therapies. Research staff should aim to approach potentially suitable patients early to facilitate obtaining endoscopic biopsies if possible and minimise the duration of treatment exposure prior to obtaining biosamples. For the avoidance of doubt, the first day of prescribed corticosteroids or advanced therapy will count as day 0.
1.2. Receipt of corticosteroids or an advanced therapy at the time of enrolment, for an indication other than inflammatory bowel disease, including psoriasis, uveitis, axial spondyloarthritis, autoimmune liver disease or microscopic colitis is not an exclusion.
2. Participants who have already undergone diagnostic lower GI endoscopy will be excluded unless a further endoscopic procedure is planned/likely where treatment-naïve biopsies could be collected or the disease is beyond the reach of diagnostic endoscopy.
2.1. The exception are patients who are recruited as inpatients with acute severe colitis (ASC) and have already undergone a colonoscopy or flexible sigmoidoscopy. These patients may be enrolled provided they meet the remainder of the eligibility criteria irrespective of whether a lower gastrointestinal endoscopy has been performed or not.
3. Presence of a stoma.

Date of first enrolment
10/03/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
The Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre

St Thomas' Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Royal Devon & Exeter Hospital (wonford)
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
St George's University Hospital
Cranmer Terrace
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
EMBL Enterprise Management Technology Transfer GmbH

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes