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Using imaging to improve the prediction of disabling Crohn's Disease

Submission date
21/01/2019

Recruitment status
No longer recruiting

Registration date
12/03/2019

Overall study status
Completed

Last Edited
30/01/2023

Condition category
Digestive System

[X] Prospectively registered
[X] 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 (CD) is an inflammatory condition of the bowel that can sometimes be very severe ("disabling"), requiring powerful drugs or surgery. It is important to treat patients with disabling disease as early as possible because this improves long-term health. However, it is not possible to give these powerful drugs to all patients because of risks and side effects. We need a better way to predict which patients will get disabling disease, and so most need this powerful treatment. A study called METRIC has just been completed to test the accuracy of bowel scanning (magnetic resonance enterography, MRE and ultrasound, US) when diagnosing CD. In the current study, the researchers will not perform any new patient interventions or have any direct patient contact. Instead, they want to determine if the MRE and US scans that the patients have already had can not only DIAGNOSE Crohn’s, but also PREDICT who will get disabling disease in the future.

Who can participate?
Patients aged 16 years or over with Crohn's disease who took part in the METRIC study, and patients who have had MRE or US scans as part of normal care (i.e. not in the METRIC study)

What does the study involve?
To find out who develops severe (disabling) disease and who does not, patients’ medical records are monitored for a longer period than originally planned in the METRIC study (increasing it from 6 months to an average of 5 years). Once it is known which patients have developed disabling disease, a statistical model is developed to test if the MRE and US scans help make better predictions about future health. If this prediction model has promise then it will be tested in a separate group of patients to prove that it works reliably for most patients with CD.

What are the possible benefits and risks of participating?
Participants do not themselves benefit from participating in this study because they would have been diagnosed with Crohn’s disease for at least 4 years and will have undergone treatment since their original diagnosis. There are no risks of participating in this study as there are no additional tests or interventions which the participants will need to undergo.

Where is the study run from?
University College Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to December 2022 (updated 10/05/2022, previously: March 2022; updated 16/03/2021, previously: September 2020)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Anvi Wadke
cctu.metricfu@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Anvi Wadke

Contact details
Trial Manager
Comprehensive Clinical Trials Unit at UCL
Institute of Clinical Trials and Methodology
2nd Floor, 90 High Holborn
London
United Kingdom
WC1V 6LJ
+44 (0)20 7907 4687
cctu.metricfu@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40339

Study information

Scientific Title
Magnetic resonance enterography as a predictor of disabling disease in newly diagnosed Crohn's Disease

Study objectives
Do MRE and ultrasound abnormalities at diagnosis predict the development of disabling Crohn's Disease?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/10/2018, London – Hampstead Research Ethics Committee, Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, Tel: +44 (0)20 7104 8127, Email: NRESCommittee.London-Hampstead@nhs.net, REC ref: 18/LO/1930

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The study aims to determine if abnormalities in MRE and SBUS at diagnosis can predict which patients are destined to develop severe ("disabling") Crohn's disease, defined using existing definitions from the literature. Patients will have had more than 4 years of follow up since they were initially diagnosed with Crohn's disease.

Magnetic Resonance Imaging (MRI) is a medical imaging technique used to visualise internal structures of the body in detail by applying magnetic field and radio frequency energy pulses. Magnetic Resonance Enterography (MRE) entails the use of MRI sequences to best show the small bowel and colon after patients drink approx 1.5 l of liquid (oral contrast) to help outline the bowel.

Ultrasound is a medical imaging technique that can generate images of the internal body structures by detecting reflections from high frequency sound waves generated by a dedicated transducer ("probe"). Small Bowel Ultrasound (SBUS) uses the same principle as all other ultrasound examinations but with specific attention directed to the small bowel.

All patients in this study will have had either MRE or SBUS at diagnosis. The researchers request access to their routine care data.

Intervention Type
Other

Primary outcome measure
Comparative predictive ability of prognostic models incorporating MRI severity scores (MEGS, MaRIA and Lémann index) to improve predictions from a model based on clinical characteristics alone to predict the development of disabling disease at 5 year follow-up. Disabling disease is defined as per modification of Beaugerie et al Gastroenterology 2006.

Secondary outcome measures
1. Comparative predictive ability of prognostic models incorporating SBUS severity scores (SSS and US-Lémann index) to improve predictions from a model based on clinical characteristics alone to predict the development of disabling disease (modified Beaugerie definition) at 5 year follow-up
2. Comparative predictive ability of prognostic models incorporating MRI severity scores (MEGS, MaRIA, Lémann index) to improve predictions from a model based on clinical characteristics alone to predict the development of Montreal B2/B3 disease or Liège severe disease at 5 year follow-up*
3. Comparative predictive ability of prognostic models incorporating SBUS severity scores (SSS and US-Lémann index) to improve predictions from a model based on clinical characteristics alone to predict the development of Montreal B2/B3 disease or Liège severe disease at 5 year follow-up*
4. Comparative predictive ability of MRE-based and SBUS-based models for disabling disease at 5 year follow-up
5. Identification of the best combination of individual MRE and SBUS features for prediction of disabling Crohn’s disease (all definitions) within 5 years of new diagnosis
6. Average per-patient and national healthcare costs incurred within 5 years of a new diagnosis of Crohn’s disease
7. Patient, disease phenotype and imaging characteristics associated with higher economic costs within 5 years of diagnosis

Overall study start date
15/03/2015

Completion date
31/12/2022

Eligibility

Key inclusion criteria
METRIC cohort:
1. Enrolled in the METRIC study, new diagnosis cohort AND
2. Formed part of the final new diagnosis cohort (i.e. with a confirmed diagnosis of Crohn's disease and underwent relevant study interventions and follow-up). METRIC new diagnosis cohort inclusion criteria were:
2.1. Aged 16 years or more
2.2. Newly diagnosed with Crohn's disease based on endoscopic, histological, clinical and radiological findings, OR

2.3. Highly suspected of Crohn's disease based on characteristic endoscopic, imaging and/or histological features but pending final diagnosis (only participants who ultimately were confirmed to have Crohn's disease will continue in this extension study) AND
3. Have given signed consent to be part of METRIC-EF

Retrospective cohort:
1. Aged 16 years or more and received a new diagnosis of Crohn's disease based on endoscopic, histological, clinical and radiological findings
2. Dedicated enteric imaging (either MRE or SBUS) acquired according to the standards of the METRIC study and performed either < 3 months after, or < 3 months prior to the new diagnosis of Crohn's disease
3. Institutional practice is to perform MRE or SBUS in all patients with newly diagnosed Crohn's disease
4. Has > 4 years clinical follow-up data, or anticipated to have such follow-up data by the time of consensus endpoint meetings (mid 2020)
5. Have given signed consent to be part of METRIC-EF

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 207; UK Sample Size: 207

Total final enrolment
198

Key exclusion criteria
METRIC cohort:
1. Enrolled in the METRIC study but not part of the final new diagnosis cohort

Date of first enrolment
25/03/2019

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
Kings Cross
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 15/59/17

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal by October 2021.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/10/2022	04/10/2022	Yes	No
HRA research summary			28/06/2023	No	No