ISRCTN03982913 https://doi.org/10.1186/ISRCTN03982913

METRIC (Magnetic resonance Enterography or ulTRasound In Crohn's disease)

Submission date
21/10/2013

Recruitment status
No longer recruiting

Registration date
05/11/2013

Overall study status
Completed

Last Edited
02/08/2023

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Crohn's disease is a type of inflammatory bowel disease that may affect any part of the digestive system, but mostly affects an area called the small bowel. The position of the small bowel in our bodies makes it difficult for doctors to view the area in order to decide if a patient has Crohn's disease and how badly the Crohn's disease is affecting the small bowel. Commonly used tests to view the small bowel are barium follow through, Colonoscopy and Computerised Tomography (CT). More recently some doctors have been using Magnetic Resonance Imaging (MRI) or Ultrasound Scanning to look at the small bowel of patients who have or are suspected of having Crohn's disease. The reason for this research is to compare MRI and Ultrasound Scanning to see which is better at detecting inflammation of the small bowel caused by Crohn's disease, and how badly the bowel is inflamed. Neither MRI nor Ultrasound Scan use X-Ray radiation, which is an advantage.

Who can participate?
The patients who will be asked to take part in this study will be men or women over 16 years old and will either be newly diagnosed (within 3 months) with Crohn's disease or will be a Crohn's patient who is suffering symptoms which cause their doctor to suspect that they are suffering from a relapse.

What does the study involve?
All patients will receive the same study-specific tests at the same time as any investigations or treatments that their doctor thinks necessary. If you take part in the study we will ask you to do the four things described below:
1. Undergo a MRI scan and an Ultrasound Scan of your bowel.
2. Provide a stool and blood sample, have an abdominal (tummy) examination and complete a short questionnaire about your symptoms.
3. Complete questionnaires about your experience of the tests you undergo and record a diary about any health-related treatment or advice you need for a period of 6 months. The questionnaires are designed to gather information on your experience of the MRI scan and how you felt after recovery from the scan, your experience of all of the imaging tests that you underwent during the first part of the study, and your quality of life throughout the study (i.e. how the entire experience made you feel and how it affects your day-to-day activities). The diary

is to record all visits to hospital and to your doctor. You will also be asked to use it to record any community care, medications and investigations that occur over the 6-month period of follow-up from recruitment.
4. Give permission for use of information that was supplied to your doctor, in order to assess your doctor's view on how the two tests affected the clinical care that you received and allow us to use your anonymised scan data for additional studies.

What are the possible benefits and risks of participating?
It is possible that the research may provide doctors with very useful information about your condition which could help in your treatment, but we cannot guarantee that this will be the case. The results may help improve the diagnosis of Crohn's in the future. Although MRI scans are regarded as a completely safe imaging method, we do not know for sure whether MRI is absolutely risk free during the early stages of pregnancy. Therefore, pregnant women should not take part in this study. Please tell your doctor if you think you might be pregnant. If your MRI and Ultrasound disagree about whether there is inflammation in your small bowel it is possible that the additional test they choose will use ionising radiation, for example a CT scan or barium follow through. Some believe that exposure to ionising radiation may cause cancer but risk from a single test is very small (around 1/1000), compared to 1/3 risk we all have anyway. MRI and Ultrasound are safe techniques that have no harmful side effects. There are certain precautions that are undertaken to ensure that individuals having the MRI scan can do so safely, for example, making sure that you have no metal in your body (e.g. a pacemaker or metal heart valve). We will ask you a set of routine questions before you are allowed to enter the MRI scanner room.

Where is the study run from?
This research will be taking place at eight hospitals in Leeds, London, Harrow, Portsmouth, Dundee, Bradford and Oxford. Two of the hospitals are in London, one of which is leading the research.

When is the study starting and how long is it expected to run?
The study is expected to start in November 2013. The whole study itself will take 2 years and 5 months to complete, in order to give time to recruit enough patients. Each patient will be involved in the research for a period of 6 months.

Who is funding the study?
National Institute for Health Research (UK), Health Technology Assessment (NIHR HTA) programme.

Who is the main contact?
Clinical Trials Unit, UCL
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA: 11/23/01, CTU/2012/008

Study information

Scientific Title
Diagnostic accuracy for the extent and activity of newly diagnosed and relapsed Crohn's disease: a multicentre prospective comparison of magnetic resonance enterography and small bowel ultrasound compared to a reference standard

Acronym
METRIC

Study objectives
Magnetic resonance enterography (MRE) will provide more detailed and accurate data than ultrasound (US) scanning for the diagnosis of Crohn's disease when compared to a reference standard.

More details can be found at: http://www.hta.ac.uk/2968
Study protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/83637/PRO-11-23-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Hampshire B, 13/09/2013, REC ref: 130054

Study design
Multicentre prospective diagnostic cohort observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied

Crohn's disease

Interventions
Diagnostic accuracy study - comparison of magnetic resonance enterography and small bowel ultrasound compared to a reference standard.

No control and no randomisation is involved.

After consent, patients will undergo MRE and USS (if not already performed as part of clinical care), provide a stool sample for calprotectin measurement, blood tests for C-reactive protein (CRP) measurement and complete a symptom diary and clinical examination for calculation of the Harvey Bradshaw Index (HBI). An EQ5D-5L questionnaire will also be completed, and patients will begin to complete a patient resource diary for months 1-3. At 3 months (range 10-20 weeks) post recruitment, patients provide a stool sample for calprotectin measurement, blood tests for CRP measurement and complete a symptom diary and clinical examination for calculation of the HBI. Wherever possible this will be done to coincide with a routine patient hospital visit. The patient will begin to complete a patient resource diary for months 4-6. At 3 and 6 months the patient completes an EQ5D-5L questionnaire. The consensus panel will convene 6 months after enrolment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Difference in per patient sensitivity of MRE and US as diagnostic tests for the correct identification and localisation of small bowel Crohn's disease, compared to a consensus reference standard.

Key secondary outcome(s))
As well as the difference in specificity of Magnetic Resonance Imaging and Ultrasound for correct identification and localisation of small bowel Crohn's disease per patient, the information provided by this study will also be used to look at Crohn's disease in the colon. There will also be separate analysis of the results of the two groups of patients: those who are newly diagnosed and those who are suffering a relapse. This will include the sensitivity and specificity from patient to patient and between the two groups.
Patients in the two groups who have received colonoscopic investigation will have their results from the MRI and US scan compared with the colonoscopy results at various sections throughout the small bowel.

A number of validated and non-validated but previously used questionnaires and case report forms (CRFs) will be used to determine the following outcomes. Clinical expertise and a consensus panel questionnaire after 6 months of patient follow-up will be used to determine the standard of reference for diagnostic accuracy against which the clinical end points will be defined.
1. How Magnetic Resonance Imaging and Ultrasound compare to each other, and to conventional imaging methods, in providing doctors with confidence in the accuracy of the diagnosis they provide patients, and how the diagnosis influences doctors' management of patients. Clinical expertise and a consensus panel questionnaire after 6 months follow-up will

define the standard of reference for diagnostic accuracy. A validated diagnostic and therapeutic impact proforma will be applied to model the effect of MRI, USS and conventional tests on patient management during the 6 months follow-up.
2. Whether there is a difference in cost of Magnetic Resonance Imaging and Ultrasound compared to each other, and to conventional imaging methods, and how important the difference in cost is when the compared accuracy of the techniques is taken into account. Clinical expertise and consensus panel questionnaire will define the standard of reference for diagnostic accuracy, EQ5D5L (taken at 3 and 6 months), patient resource diary for 6 months and patient experience questionnaire.
3. How well radiologists agree with each other when they perform an Ultrasound Scan of the bowel and whether it is possible to improve the Ultrasound Scan technique by asking patients to drink a liquid before the scan (called hydrosonography). Clinical expertise and consensus panel questionnaire after 6 patient months follow-up will define the standard of reference for comparative diagnostic accuracy. CRFs will record radiologist confidence in their diagnosis.
4. How patients felt about their experience of Magnetic Resonance Imaging, compared to their experience of Ultrasound Scanning. Patient experience questionnaire after completing all imaging tests.
5. Whether is it possible to enhance the Magnetic Resonance Imaging test by adapting the technique and whether this improves disease detection, confidence in diagnosis and assessment of the activity of the disease. Clinical expertise and consensus panel questionnaire will define the standard of reference for diagnostic accuracy.
6. Whether there is a difference between how individual doctors read the results of imaging tests which might affect how reliable the diagnosis is from patient to patient. Clinical expertise and consensus panel questionnaire will define the reference standard for diagnostic accuracy, radiologist will record their interpretation of MRI on study CRFs.

Completion date
31/05/2016

Eligibility

Key inclusion criteria
Patient inclusion criteria (new diagnosis)
1. Patients (≥ 16 years) undergoing or having undergone colonoscopy and either: newly diagnosed (within 3 months) with Crohn's disease based on endoscopic, histological, clinical and radiological findings, OR highly suspected of Crohn's disease based on characteristic endoscopic, imaging and/or histological features but pending final diagnosis.
2. Patient must be able to provide informed consent.

Patient inclusion criteria (suspected relapse)
1. Patients (≥ 16 years) with a known diagnosis of Crohn's disease with high clinical suspicion of luminal relapse indicating radiological investigation. High clinical suspicion defined as objective markers of inflammatory activity (raised C Reactive Protein >8 mg/l OR raised calprotectin >100), OR symptoms suggestive of luminal stenosis (including obstructive symptoms such as colicky abdominal pain, vomiting) OR abnormal endoscopy suggesting relapse.
2. Patient must be able to provide informed consent.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
335

Key exclusion criteria
Exclusion criteria (all patients)
1. Any psychiatric or other disorder likely to impact on informed consent
2. Evidence of severe or uncontrolled systemic disease which make it undesirable for the patient to participate in the study
3. Pregnancy
4. Contraindications to Magnetic Resonance Imaging (e.g. cardiac pacemaker, severe claustrophobia, inability to lie flat).

Patient exclusion criteria (new diagnosis)
1. Final diagnosis other than Crohn's disease
2. Patients undergoing surgical resection prior to colonoscopy

Date of first enrolment
04/11/2013

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trials Unit
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) grant ref: 11/23/01, DoH reference: 106897

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No
Results article	results	01/08/2019	23/08/2019	Yes	No
Protocol article	protocol	11/08/2014		Yes	No
Other publications	Post hoc analysis comparing ultrasound with MRI and histology	01/08/2023	02/08/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes