ISRCTN73466412 https://doi.org/10.1186/ISRCTN73466412

Comparative study of magnetic resonance defaecography and evacuation proctography in evaluation of pelvic floor dysfunction

Submission date 18/06/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/07/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/02/2018	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Constipation is common in western societies, affecting women more often than men. Obstructive defecation (OD), an inability to pass stools, may affect up to 12.3% of women. Traditionally Evacuation Proctography (EP) has been used to evaluate the causes of OD. It is an x-ray test that shows the rectum and anal canal as they change during a bowel movement. However, in the last 20 years Magnetic Resonance Defaecography (MRD) has been increasingly studied for the evaluation of OD. MRD is a test that uses radio waves and a strong magnet to obtain high quality images during a bowel movement, avoiding the use of radiation associated with EP. There are only a few small studies comparing EP and MRD with conflicting results. Further studies are therefore needed. The aim of this study is to determine whether MRD or EP provides more useful information for the evaluation of patients with symptoms of OD.

Who can participate?
Patients aged 18 to 90 with symptoms of OD

What does the study involve?
Participants are asked questions about the severity of their symptoms and undergo both EP and MRD in a random order. Based on the results of the first test a hypothetical management plan is made. Once the second test is performed, the consultant surgeon reviews the management plan and any changes are recorded. After both the investigations are complete, participants are given a simple preference questionnaire, which they may return immediately or post at a later date (within 2 weeks).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Heart of England NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2012 to March 2013

Who is funding the study?
Heart of England NHS Foundation Trust (UK)

Who is the main contact?
Mr Michael Feretis
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Contact information

Type(s)
Scientific

Contact name
Mr Michael Feretis

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011065GS

Study information

Scientific Title
Comparative study of magnetic resonance defaecography and evacuation proctography in evaluation of pelvic floor dysfunction

Study objectives

There are only a few studies comparing evacuation proctography (EP) and magnetic resonance defecography (MRD) and they are limited by their small sample sizes and conflicting results. Hence further studies are required comparing these two imaging modalities to help inform clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Ethics Committee, 07/12/2011, ref:11/WM/0259

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Pelvic floor dysfunction/obstructive defecation

Interventions
Patients who consent to take part in the study will undergo both magnetic resonance defaecography and evacuation proctogram. However, the sequence in which these investigations take place will be randomized. Randomization will be done using block randomisation. Imaging requested for study patients will be anonymised. One subspecialist radiologist will report MRD and a second radiologist will report EP, both blinded to clinical findings and reports/images of the other imaging modality. Study patients who fail to evacuate or have suboptimal imaging for various reasons will be recalled for a further attempt at the discretion of the Radiologist or pelvic floor multi-disciplinary team in accordance with standard clinical practice. However, results of the first attempt at imaging only will be included for research data collection purposes. This is because failure to evacuate is one of the outcome measures.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Comparison of proportions and grade of pathology/prolapse in posterior compartment detected by EP and MRD (rectocele, recto-rectal intussusception, perineal descent, enterocele, ability to evacuate).

Secondary outcome measures
1. Comparison of proportion & grade of prolapse in anterior and middle compartment detected by EP and MRD (cystocele, uterine/vaginal vault prolapse)
2. Concordance between findings of EP and MRD
3. Effect on hypothetical management plan by each investigation and if any subsequent change in management after the other investigation
4. Patient preference and acceptability questionnaire

Overall study start date
30/03/2012

Completion date
30/03/2013

Eligibility

Key inclusion criteria
1. Age >18 and <90
2. Symptoms of obstructive defecation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
57

Key exclusion criteria
1. Age <18 or >90
2. Patients with previous operations for obstructive defecation
3. Patients with colorectal cancer
4. Mentally incapacitated
5. Patients who do not understand English

6. Patients for whom magnetic resonance imaging is contraindicated (pacemaker, aneurismal clips)
7. Patients with positive pregnancy test

Date of first enrolment
30/03/2012

Date of final enrolment
30/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Good Hope Hospital
Birmingham
United Kingdom
B75 7RR

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Sponsor details
Research and Development Directorate
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
England
United Kingdom
B9 5SS

Sponsor type
Hospital/treatment centre

Website
http://www.heartofengland.nhs.uk/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart of England NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration