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

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

### Contact details
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# Additional identifiers

### Protocol serial number
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

### Study type(s)
Diagnostic

### 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(s)
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).

### Key secondary outcome(s))
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

### Completion date
30/03/2013

## Eligibility

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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

### Organisation
Heart of England NHS Foundation Trust (UK)

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Heart of England NHS Foundation Trust (UK)

# 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |