

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

<b>Submission date</b> 18/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2018	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
micferetis83@hotmail.co.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Michael Feretis

**Contact details**  
General surgery Secretaries  
Good Hope Hospital  
Rectory Road  
Sutton Coldfield  
Birmingham  
United Kingdom  
B75 7RR  
07912118028  
micferetis83@hotmail.co.uk

## 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