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# MEDAL: MRI to Establish Diagnosis Against Laparoscopy

**Submission date**
16/02/2012

**Recruitment status**
No longer recruiting

**Registration date**
20/02/2012

**Overall study status**
Completed

**Last Edited**
27/07/2018

**Condition category**
Signs and Symptoms

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

## Plain English summary of protocol

Background and study aims
Chronic pelvic pain (CPP) is defined as pain in the pelvic and lower abdominal area that lasts six months or longer. In primary care, the proportion of people per year with CPP is 38/1000 in women aged 15-73, a rate similar to that of asthma (37/1000) and chronic back pain (41/1000). There is no effective way to manage CPP. Only 20-25% of patients respond to conservative treatment (that is, treatment that avoids extreme drug therapy or operations). CPP is still the single most common reason for referral to a gynaecology clinic, accounting for 20% of all outpatient appointments. Five percent of all new gynaecological appointments are for CPP. At present there is great variation in clinical practice for diagnosis and management of CPP. There are many cases of CPP in both primary and secondary care. Patients often see several health professionals before their underlying condition is identified. This wastes both the patients' time and NHS resources. A diagnosis of CPP of unknown origin is given if a cause for the pain can't be found. That does not mean that CPP of unknown origin is in the mind; also, severity of pain may not be related to severity of underlying disease, as seen in endometriosis where stage of disease is poorly related to reported pain. In a group of 487 women recruited into a trial of neuroablation (surgery that blocks nerve tissue), 54% of women had no identifiable disease at laparoscopy (keyhole surgery), whilst 31% had endometriosis, 5% had pelvic inflammatory disease and 17% had adhesions. Around 11% had more than one finding. The aim of this study is to find out if magnetic resonance imaging (MRI) can replace laparoscopy in women who have CPP or help to prioritise treatment based on need. The study will look at the proportion of women for whom MRI is accurate enough to replace laparoscopy following evaluation of their symptoms. The aim is to find out whether the 'post-laparoscopy diagnoses' are better for the patient than 'post-MRI diagnoses' (i.e. whether it has helped to find many more disease-related conditions) or whether laparoscopy could have been avoided.

The objectives of the study are:
1. To compare the accuracy of the post-MRI diagnoses and the post-laparoscopy diagnoses for a) the absence of any disease-related cause and b) the main diseases causing CPP.
2. To find out if laparoscopy is more useful than MRI and whether both tests are more useful than information collected at the start of the study (medical history/clinical examination /ultrasound).
3. To find out how much impact MRI and laparoscopy have on diagnostic decision-making, and to

compare how good post-MRI diagnoses and the post-laparoscopy diagnoses are.
4. Estimate the number of women who should have a diagnostic laparoscopy or laparoscopy as a treatment.
5. To find out, using mathematical techniques, the symptoms that show which women would benefit most from MRI and which women would not benefit.
6. To create a decision-making model to work out the cost-effectiveness of MRI in reducing the need for laparoscopy.

Who can participate?
Women aged 16 and over who have been referred to a gynaecologist with CPP where the need for a laparoscopy is established

What does the study involve?
Participants have an MRI scan before laparoscopy but the report is not given to the gynaecologist, unless there is a critical finding such as possible cancer cells which might spread, so the results do not affect how treatment proceeds. A diagnostic laparoscopy is also carried out and together with information from medical history, examination and ultrasound, a post-laparoscopy diagnosis is produced. Follow-up at 6 months, which looks at response to treatment and results of additional tests are also obtained, and are used by a panel of experts according to a previously agreed step-by-step procedure to decide the reference diagnosis.

What are the possible benefits and risks of participating?
Risks of MRI are rare, but this test can theoretically produce heat, which is absorbed by the body tissue, but this is not known to produce any side effects. A laparoscopy involves minimal damage to body tissues and is, on the whole, safer than 'open' operations such as laparotomy. Possible complications of laparoscopies include damage to organs inside the abdomen and wound infections. Women having a laparoscopy need a general anaesthetic and, as with all anaesthetics, there is a risk of complications, particularly in obese women. These risks are extremely small, as only experienced surgeons/radiologists are allowed to take part. By having an additional MRI scan before the laparoscopy, any abnormalities such as cancer cells are highly likely to be found. These may be picked up during the laparoscopy, but if found earlier (in the MRI), treatment can be started before the laparoscopy is carried out.

Where is the study run from?
The study sponsor is Queen Mary University of London (UK) and the coordinating centre is Birmingham Clinical Trials Unit, University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
December 2011 to November 2015

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

Who is the main contact?
Mr Lee Priest
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# Contact information

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Scientific

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# Additional identifiers

**Protocol serial number**
HTA 09/22/50

# Study information

**Scientific Title**
Can magnetic resonance imaging scan replace or triage the use of laparoscopy in establishing a diagnosis amongst women presenting in secondary care with chronic pelvic pain?

**Acronym**
MEDAL

## Study objectives
MRI may be a useful diagnostic tool for adenomyosis, deep infiltrating endometriosis and ovarian endometriomas. However, its use for the differential diagnosis of other pathological causes of chronic pelvic pain (CPP) has not yet been fully investigated. Existing research does not tell us whether MRI can replace laparoscopy in the differential diagnosis of underlying conditions. Compared to laparoscopy, MRI may be more or equally accurate, is less invasive, carries fewer risks, is easier to do, does not require a general anaesthetic, is less uncomfortable for patients, has shorter waiting times and is cheaper. MRI findings may also assist in patient management for example referral could be to a gynaecologist specialising in the particular problem discovered, rather than a general gynaecologist.

This study will delineate the accuracy of MRI against a reference diagnosis derived from an expert independent panel and examine the cost-effectiveness of the alternative pathways to diagnosis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee East Midlands - Nottingham 1, 16/08/2011, ref: 11/EM/0281

## Study design
Multicentre diagnostic accuracy study with a paired design

## Primary study design
Observational

## Study type(s)
Diagnostic

## Health condition(s) or problem(s) studied
Chronic pelvic pain

## Interventions
MRI and laparoscopy compared with reference standard.

Those who are eligible and consent to participation in the diagnostic study will have a MRI scan scheduled before the diagnostic laparoscopy.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
To assess if MRI can replace or triage the need for laparoscopy in women presenting with Chronic Pelvic Pain (CPP). The trialists will determine the proportion of women for whom MRI is sufficiently accurate to replace laparoscopy following evaluation of presenting characteristics.

This will be completed by ascertaining if the 'post-laparoscopy diagnoses' has added any clinical benefit to the 'post MRI diagnoses' (i.e. whether it has diagnosed substantially more pathological conditions) or whether it could have been avoided.

### Key secondary outcome(s))
1. To compare the diagnostic accuracy of the post-MRI diagnoses and the post-laparoscopy diagnoses for the absence of any pathological cause (i.e. idiopathic) and the main pathological causes of CPP
2. To determine the added value of laparoscopy over MRI and both tests over information collected at baseline (history/clinical examination/ultrasound)
3. To quantify the impact that MRI and laparoscopy have on diagnostic decision-making, and to compare the certainty of the post-MRI diagnoses and the post-laparoscopy diagnoses
4. Estimate the proportion of women for whom a diagnostic and/or therapeutic laparoscopy is indicated
5. To determine, using multiple logistic regression, the presenting characteristics which identify the subgroups who would benefit most from MRI and conversely, those who would not benefit
6. To perform a decision-analytic model based economic evaluation determining the cost-effectiveness of MRI in reducing the need for laparoscopy

### Completion date
24/11/2015

## Eligibility

### Key inclusion criteria
1. Women aged 16 and over
2. Women referred to a gynaecologist with CPP
3. Women who have given written informed consent
4. Need for a laparoscopy is established and the patient wishes to proceed with it

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 years

### Sex
Female

### Key exclusion criteria
1. Women who have had a hysterectomy
2. Women who are pregnant
3. Women unable to give consent through incapacity or inability to speak English and lack of suitable interpreter

4. Women who are considered to definitely require an MRI, based on ultrasound and history
5. Women with an identifiable cause of CPP for which treatment can be initiated

**Date of first enrolment**
09/12/2011

**Date of final enrolment**
01/09/2013

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Barts and the London School of Medicine and Dentistry**
London
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E1 2AB

# Sponsor information

**Organisation**
Queen Mary, University of London (UK)

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Lee Middleton (l.j.middleton@bham.ac.uk).

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2018 | | Yes | No |
| Protocol article | protocol | 04/12/2013 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |