ISRCTN84527805 https://doi.org/10.1186/ISRCTN84527805

# Diagnostic accuracy of MRI, diffusion-weighted MRI, FDGPET/CT and Fluoro-ethyl-choline PET /CT in the detection of lymph node metastases in surgically staged endometrial and cervical carcinoma

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| **Submission date**<br>25/11/2011 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>14/12/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/04/2022 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-mri-scan-pet-ct-scan-cervical-womb-cancer-mapping

## Contact information

**Type(s)**
Scientific

**Contact name**
Miss Hanna Nicholas

**Contact details**
Old Anatomy Building
Rutland Place
Charterhouse Square
London
United Kingdom
EC1M 6BQ
-
mapping@qmcr.qmul.ac.uk

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT01836484

### Clinical Trials Information System (CTIS)
2011-001290-78

### Protocol serial number
10984

# Study information

### Scientific Title
Diagnostic accuracy of MRI, diffusion-weighted MRI, FDGPET/CT and Fluoro-ethyl-choline PET /CT in the detection of lymph node metastases in surgically staged endometrial and cervical carcinoma: a non-randomised study

### Acronym
MAPPING

### Study objectives
The aim of this trial is to demonstrate whether leading edge imaging technology [diffusion-weighted magentic resonance imaging (DW-MRI), F18-fluoroethylcholine (FEC)- PET/CT and 18F-fluorodeoxyglucose (FDG)-Positron emission tomography (PET) / computed tomography (CT)] can identify lymph node metastases with sufficient accuracy to allow non-invasive lymph node staging or minimally invasive lymph node sampling in the place of surgical lymphadenectomy in patients with endometrial and cervical carcinoma at risk of nodal metastases.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Primary study design
Observational

### Study design
Non-randomised; Not Specified

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Cervix, Endometrium

### Interventions
DW-MRI, DW-MRI; FDG-PET/CT, FDG-PET/CT; FEC-PET/CT, FEC-PET/CT; Study Entry: Registration only

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Comparison of DW-MRI, FDG-PET/CT, FEC-PET/CT with histology; Timepoint(s): Within NHS Cancer Plan for pre-operative care for Cancer Patients

### Key secondary outcome(s)
1. To compare the diagnostic accuracy of FDG-PET/CT, DW-MRI and FEC-PET/CT to each other in the preoperative diagnosis of metastases in patients with endometrial and cervical cancer
2. To determine whether one imaging modality performs better than the other in particular sub-groups, such as, particular histological sub-groups
3. To determine whether FEC-PET/CT uptake reflects changes in histologic findings

### Completion date
01/06/2015

## Eligibility

### Key inclusion criteria
1. Females older than 18 years; (no upper limit)
2. Patients with histologically confirmed cancer of the cervix or endometrium
2.1. demonstrated clinically and/or on MRI. In patients with advanced disease being considered for chemoradiotherapy treatment, patients may be considered for entry if paraaortic nodal lymphadenectomy is being used to inform radiotherapy planning
2.2. In patients with endometrial cancer, a) stage 1A with myometrial invasion or any higher stage and grade 3 histology with lymphovascular space invasion, b) stage 1A with myometrial invasion or any other higher stage and serous papillary or clear cell subtypes. The MDT decision may be based on the combination of tumour characteristics on histology, clinical and imaging findings.
3. No contraindication to FDGPET/CT, FECPET/ CT or MRI
4. Fit for surgical lymphadenectomy, as determined by the local MDT. The patient should also be considered fit for extended field radiotherapy in cases where lymphadenectomy is being undertaken to inform radiotherapy planning
5. Able and willing to give written informed consent and to comply with the study protocol procedures; Target Gender: Female ; Lower Age Limit 18 no age limit or unit specified

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex

All

### Total final enrolment
147

### Key exclusion criteria
1. Known contraindication to MRI or PET/CT scan
2. Known allergy to FDG or FEC
3. Not considered fit for lymphadenectomy (open or laparoscopic) or, where appropriate, radiotherapy, as determined by the local MDT
4. If the patient is pregnant or breastfeeding
5. Females of childbearing potential must be willing to use an effective method of contraception (hormonal or barrier method of birth control; abstinence) from the time consent is signed until 6 weeks after treatment discontinuation
5. Note: subjects are not considered of childbearing potential if they are surgically sterile (they have undergone bilateral tubal ligation or bilateral oophorectomy) or they are postmenopausal
6. Females of childbearing potential must have a negative pregnancy test prior to being registered for the study
7. Medical or psychiatric illness, which makes the patient unsuitable or unable to give informed consent

### Date of first enrolment
01/02/2012

### Date of final enrolment
01/06/2015

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### Old Anatomy Building
London
United Kingdom
EC1M 6BQ

## Sponsor information

### Organisation
Barts and The London Trust (UK)

### ROR

https://ror.org/00b31g692

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research UK (CRUK) (UK)

**Alternative Name(s)**
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 02/01/2021 | 14/04/2022 | No | No |