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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

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

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Additional identifiers

EudraCT/CTIS number
2011-001290-78

IRAS number

ClinicalTrials.gov number
NCT01836484

Secondary identifying numbers
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

Study design
Non-randomised; Not Specified

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

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
England

United Kingdom

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

Sponsor information

Organisation
Barts and The London Trust (UK)

Sponsor details
Joint Research Office
24-26 Walden Street
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E1 2AN

Sponsor type
Hospital/treatment centre

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/04/2020

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

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