ISRCTN57474502 https://doi.org/10.1186/ISRCTN57474502

Comparative effectiveness of magnetic resonance (MR) imaging in women with breast cancer

Submission date 19/06/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/06/2002	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-magnetic-resonance-imaging-to-help-diagnose-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 99/27/05

Study information

Scientific Title
Comparative effectiveness of magnetic resonance (MR) imaging in women with breast cancer

Acronym
COMICE

Study objectives
Study hypothesis added as of 10/06/2008:
The overall aim of this randomised controlled trial is to determine the potential benefits to the patient and to the NHS of the addition of MR imaging to the routine techniques employed for loco-regional staging of primary breast cancer.

Please note that as of 10/06/2008 this trial record was extensively amended. The following changes have taken place:
1. Anticipated end date has been updated from 30/09/2008 to 31/01/2008
2. Study hypothesis was added
3. Information on ethics approval was added
4. Participants - exclusion criteria were added
5. Secondary outcome measures were added

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/01/2008 to 30/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 10/06/2008:
The North West Multi-centre Research Ethics Committee. Date of approval: 04/09/2001 (ref: MREC 01/8/61).

In addition, each participating centre received an approval from a local ethics committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Patients are randomised to receive either the standard triple assessment (mammography, ultrasound, core biopsy/fine needle aspiration [FNA]) or standard triple assessment plus an MR scan.

Randomised controlled trial of women with primary breast cancer (PBC) scheduled for WLE following triple assessment (TA). Participants will be recruited over 36 months and a minimisation algorithm used to balance the random allocation in respect of key prognostic variables. Women will be randomised to MRI before WLE or will proceed directly to WLE. MR images will be evaluated by radiologists with prior knowledge of XRM and US results. Following review of XRM, US & MRI three outcomes are possible: MR findings equivalent to XRM/ US - proceed to WLE; multifocal lesions present or tumour size greater on MRI - surgical management reviewed; or MC disease detected. If MC lesions are <5mm patients proceed to WLE, but if >5mm MR-localised, US-guided FNAC/ core biopsy required. Biopsy -ve patients will proceed to WLE, but if +ve surgical management will be reviewed. Repeat MRI on women with < 5mm lesions or FNAC/ core biopsy -ve >5mm lesions will be performed at 1 year. Detailed serial sectioning of excised specimens will allow correlation with results of XRM, US and MRI.

Setting: Multi-centre, hospital based study involving multidisciplinary groups in Bolton, Cardiff, Hull/ Grimsby, Leeds, London (St Mary's) and Newcastle/ Gateshead. High field (1.5T) MR systems with dedicated breast coils, fast scanning capabilities and post-processing facilities are already in place.

Approximately 150-500 primary breast cancers are detected at each centre p.a., of which approximately 50% are scheduled for WLE, providing a potential trial population of 3,500. The study would be coordinated through Northern & Yorkshire Clinical Trials & Research Unit at the University of Leeds and Wales Cancer Trials Network in Cardiff. Target Population: Women with FNAC or core biopsy proven PBC scheduled for WLE after conventional triple assessment, but excluding those with contraindications to MRI or contrast medium administration. Health technologies being assessed: MRI: Multiple thin-slice (in-plane resolution 1.3 x 1.3 mm; thk 4 mm) 3D, contrast-enhanced (0.1 mmol Gd-DTPA/ kg body weight) fast spoiled gradient-echo MR sequences (temporal resolution 45 seconds), analysed using robust, easily implemented techniques (signal intensity time course evaluation) will be combined with high resolution (0.7 x 0.9 mm in plane) post-contrast fat- suppressed MR imaging for morphological information. This will be compared with XRM (medio-lateral oblique, cranio- caudal ñ paddle/ axillary views) and whole breast US (7.5 - 13 MHz linear array transducer).

Sample size: Assuming MRI will reduce overall re-operation/ mastectomy rates after WLE from 15 to 10%, 1,840 women are required to detect a benefit with 90% power and 2-sided significance level of 5%. Project timetables/ recruitment rate: 0-3 months: study-specific data-base; preparation of MREC application; piloting of data collection forms; 3-39 months: patient recruitment & data collection; 49-51 months: analysis of intermediate and 66-69 months analysis of final trial data & preparation of manuscript(s). Assuming 50% of women with PBC are

scheduled for WLE, a recruitment rate of 52.5% is required, and is considered achievable with study-specific Research Nurses.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Cost and outcome measures:
1. Comparison of re-operation/ mastectomy/RTX rates after TA or TA and MRI.
2. IBTR rate at 5 yrs for patients imaged ñ MRI.
3. Extrapolated life expectancy and quality adjusted life expectancy.
4. Quantification of patient satisfaction with management decisions and quality of life measurements using FACT-B, HADS score, EQ-5D and ad-hoc questionnaire to examine concerns about tumour recurrence.
5. Differential resource implications in first year of TA vs TA + MRI, including measurement of indirect and personal costs incurred by patients.
6. Estimation of later costs due to differential rates of recurrence related to life expectancy and quality adjusted life expectancy.
7. Determination of sub-groups most likely to benefit from addition of DCE-MRI. 8. Effectiveness of XRM, US and DCE-MRI imaging.

Secondary outcome measures
Added as of 10/06/2008:
1. Recurrence rate
2. Chemotherapy/radiotherapy interventions
3. Quality of life and patient satisfaction
4. Risk factors for referral for MR imaging
5. Effectiveness of imaging
6. Change in clinical management
7. Clinical significance of <5 mm MR-only detected lesions

Overall study start date
01/06/2001

Completion date
30/09/2008

Eligibility

Key inclusion criteria
Patients scheduled for wide local excision for primary breast cancer

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1,840

Total final enrolment
1623

Key exclusion criteria
Added as of 10/06/2008:
1. Medically unstable
2. Known contraindication to magnetic resonance (MR) scanning
3. Known to have had an allergic reaction associated with previous administration of paramagnetic contrast agent or have a severe allergic diathesis
4. Require renal dialysis
5. Have undergone chemotherapy/ hormonal therapy for cancer of the contralateral breast (or other sites) in the previous 12 months or have chemotherapy planned to any site before their breast surgery
6. Have had surgery or radiotherapy for cancer to the ipsilateral breast
7. Have had surgery to the ipsilateral breast within the previous 4 months for benign breast disease
8. Have a history of serious breast trauma within the last 3 months
9. Pregnant or breast feeding
10. Disability preventing MR scanning in the prone position
11. Under the care of a breast surgeon recruiting into the ALMANAC Trial

Date of first enrolment
01/06/2001

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Magnetic Resonance Imaging
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Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results on cost effectiveness	01/01/2010		Yes	No
Results article	results on clinical effectiveness	13/02/2010		Yes	No
Plain English results			25/10/2022	No	Yes