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MAMMO-50: mammographic surveillance in breast cancer patients aged 50 years and over

Submission date 26/02/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 26/02/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 21/01/2026	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/This-trial-looking-follow-up-mammograms-women-over-50-who-have-had-breast-cancer

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Additional identifiers

Protocol serial number
16250

Study information

Scientific Title
MAMMO-50: mammographic surveillance in breast cancer patients aged 50 years and over: a randomised controlled trial

Acronym
MAMMO-50

Study objectives
The Government`s Cancer Reform Strategy recommends breast cancer patients be supported in self-care and have personalised risk-adjusted follow-up to meet their needs. As young age is a strong predictor of invasive and non-invasive 'second' breast cancer (i.e., recurrence on treated side or new cancer in opposite breast), current NICE 2009 guidance recommends patients diagnosed up to 50 years have mammograms annually. For those patients aged 50 or older at diagnosis, there is no clear evidence or consensus amongst specialists on risk factors to advise the optimum frequency or duration of follow-up mammograms.

Type of breast surgery (mastectomy or conservation) does not affect long-term survival. However, 3 years after diagnosis, second breast cancers are found less frequently by mammography in mastectomy patients than those patients who have had conservation surgery. Early detection of second cancers or metastasis is more likely to occur via patient self-examination between mammograms than by specialist clinic visit. A patients ability to self-check and report concerns could be improved by alternative follow-up regimens including questionnaires and/or contact with nurses GPs, radiographers or internet access. There have been no randomised controlled trials in this setting.

In order to provide sound evidence for future management, this clinical trial aims to establish if patients aged 50 years or over can be identified who require less frequent mammographic surveillance whilst investigating alternative methods of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 11/12/2013, ref: 13/WM/0419

Study design
Randomised; Interventional and Observational; Design type: Treatment, Cohort study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
For the purposes of MAMMO-50, centres will utilise digital imaging in line with the national roll-out of digital screening mammography in 2010. Digital mammography offers advantages in terms of image quality, increased sensitivity in important subgroups (e.g., women with dense breasts) and reduced examination time that permits a greater opportunity for patient contact with the radiographer or breast care nurse. It is also reported to deliver significantly less radiation than conventional mammography.

In addition to the mammogram, eligible patients will be asked to complete the MAMMO-50 patient questionnaire booklet, delivered at the time of their mammogram or clinical follow-up, which will include questions on their general health, health resource use and adherence to prescribed maintenance therapy such as Tamoxifen or Arimidex.

In addition the patient and public Involvement (PPI) component of the study will evaluate adequacy of current information offered as standard to patients as well as effective ways of collecting quality of life data for those patients consenting to be part of the QoL and/or qualitative sub-studies.

Intervention Type
Other

Primary outcome(s)
1. Disease-specific survival
2. Cost effectiveness
The first Mammo-50 patient questionnaire booklet, which will include general questions, Health Resource Use forms and EQ-5D-5L, must be given to patients after written consent is obtained but prior to randomisation. Further Mammo-50 patient questionnaire booklets will be administered around the time of scheduled mammograms, i.e. annually from randomisation for more frequent mammogram schedule and 2 or 3 years for the less frequent mammogram schedule, up to 10 years post curative surgery.

Key secondary outcome(s))
1. Recurrence (time to recurrence, type of recurrence and features of recurrence plus new primary in ipsilateral breast and new primary in contralateral breast) using questionnaire and data linkage. The NCIN lead registry for breast cancer will match the MAMMO-50 cohort against the national cancer registration database at 3-yearly intervals for 3 years (3, 6 and 9 years after

randomisation). Details of recurrent breast cancers (local, regional and distant) will be provided as will dates and causes of death where appropriate. The histological characteristics of ipsilateral breast tumour recurrences (IBTR) and contralateral new primaries will be recorded and the Nottingham Prognostic Index (NPI) calculated and compared to the NPI of the original tumour. These characteristics will include invasive and in situ tumour size, histological grade, histological type, vascular invasion status, ER, PR and HER-2 status, in those tumours treated by immediate surgical resection. Nodal status will be recorded in those who have a further nodal procedure. In tumours treated with systemic therapy and no surgery (this is common if metastatic disease is found at the time of recurrence) tumour type and grade and receptor status will be ascertained from the diagnostic core biopsy and lesion size estimated from imaging
2. Number of referrals back to the hospital system
3. Long-term survival (20 years post-surgery) using ONS flagging

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Female, age >= 50 at initial cancer diagnosis
2. Excised invasive breast cancer with local treatment completed
3. Three years post curative surgery date
4. Written informed consent for the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
6150

Key exclusion criteria
1. Breast cancer recurrence, new breast cancer primary or any new malignancies
2. Previous diagnosis of malignancy unless managed by surgical treatment only and disease free for 10 years or previous basal cell carcinoma of skin, cervical intraepithelial neoplasia or in situ ductal carcinoma of the breast treated with surgery only

Date of first enrolment
01/09/2013

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Warwick Medical School Clinical Trials Unit
-
Coventry
England
CV4 7AL

Study participating centre
115 participating centres
-
NO COUNTRY SPECIFIED, assuming England
England
-

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

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
Data collected within the Mammo-50 trial will be made available to researchers whose full proposal for their use of the data has been approved by the Mammo-50 Trial Management Group and whose research group includes a qualified statistician. Any requests for access to the trial data should be sent to the Chief Investigator, Professor Janet Dunn, who will inform the data custodian, the University of Warwick. Please send requests via email to mammo-50@warwick.ac.uk. Each data sharing request should include the purpose, scope, data items requested, analysis plan, acknowledgement of the trial management team and evidence of appropriate ethical approvals. Requestors who are granted access to the data will be required to complete a data-sharing agreement, which will be signed by the requester, sponsor and principal investigator(s). We anticipate that data sharing will be possible after the publication of the primary endpoint of the trial and will remain available up to 5 years from the end of the trial.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2025	03/02/2025	Yes	No
Results article	Cost-effectiveness and budget impact analysis	06/11/2025	07/11/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	07/07/2021	23/05/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes