Nationwide cluster-randomised trial of extending the NHS breast screening age range in England

Contact information
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Additional identifiers
EudraCT number
ClinicalTrials.gov number
Randomisation of small groups (cluster randomisation) of trial participants determines which groups of women are offered one additional screening invitation before age 50 and which are not, and which groups of women are offered additional screening after age 70 and which are not. For each separate age range the trial will be able to compare over the following years those women in the clusters invited for screening and those women in the clusters not invited for screening; women will be followed up by linkage to NHS records, including cancer and hospital records, to assess the risks and benefits of the additional screening. It will also take at least the mid 2030s before results are known.

The findings will be monitored, analysed and reported as two entirely separate trials. One is a trial among younger women (randomly allocated at age 47-48) to additional screening invitation in overall life effect of an extra screening invitation 3 years before routine screening would normally have begun. The other is a trial among older women (randomly allocated at age 71-72) to additional screening invitation or screening the effects of an extra screening invitation among those who have had their first routine screening invitation.

The trial began in 2009 and is eventually expected to include at least ten million women aged 47-48 and 1 million aged 71-72. It will involve about 7 of the 61 breast screening units in England. The units agreed not to participate are mainly those using non-standard methods for inviting women for screening.

**Previous Hypothesis:**
Currently, all women aged 50-60 are invited to breast screening every three years. In 2007 the Cancer Reform Strategy announced that from 2012 the NHS Breast Screening Programme (HMBSP) would cover women aged 47-73. As capacity does not allow for full introduction滚动 across the whole of England, the age extension is being phased in with full coverage intended from 2013 although who may be delayed due to recent unexpected perturbations in digital mammography.

To date there is limited evidence on the net benefit of extending invitations or lowering the age range for breast screening; no trial has tested the added value of one extra screen within an existing screening programme.

This study proposes randomizing the phasing of the age extension and collecting information on breast cancer incidence and mortality over the following 10 years. This would provide unbiased evidence on the net effects of extending the age range for breast screening. The findings have the potential to inform future screening policy in the UK and elsewhere.
This study is seeking volunteers aged 50 to 70 years with a previous history of breast cancer, who have been referred for breast screening.

The study is designed to assess the effectiveness of increasing the age range for breast screening up to 70 years. The findings have implications for future screening policy in the UK and elsewhere.

The study will proceed regardless of whether the study has been approved or not.

The study is funded by the National Institute for Health Research (NIHR) and is being conducted in a consortium of hospitals and health authorities.

Data on the number of participants, duration of the study, and the number of screening rounds will be recorded in a database. The data will be used to assess the impact of changing the age range for breast screening.

The study is open to volunteers aged 50 to 70 years with a previous history of breast cancer, who have been referred for breast screening.

The study is funded by the National Institute for Health Research (NIHR) and is being conducted in a consortium of hospitals and health authorities.

Ethical approval
1. The study has been approved by the National Research Ethics Committee and the local ethics committee.
2. The study is being conducted in accordance with the Declaration of Helsinki.
3. The study will be monitored by an independent data monitoring committee.
4. The study will be published in a peer-reviewed journal.

Study design
- Multi-centre, cluster randomised controlled trial.
- Double-blind, placebo-controlled.
- Parallel groups.

Participants
- Women aged 50 to 70 years with a previous history of breast cancer.
- Women who have been referred for breast screening.

Interventions
- Women in the intervention group will receive additional targeted education on breast cancer screening.
- Women in the control group will receive standard breast cancer screening.

Outcomes
- The number of women who receive breast cancer screening.
- The number of women who are diagnosed with breast cancer.

Analysis
- Intention-to-treat analysis.
- Time-to-event analysis.

Funding
- National Institute for Health Research (NIHR).

Study implementation
- The study will be conducted in a consortium of hospitals and health authorities.
- The study will be monitored by an independent data monitoring committee.
- The study will be published in a peer-reviewed journal.

Protocol
- Version 1.0, dated 01/2014.
- The protocol has been approved by the National Research Ethics Committee and the local ethics committee.
- The protocol has been revised to include additional outcomes and analyses.

Patient information sheet
- Available at [link].

Contact
- For more information, please contact [contact details].
Patient Information Sheet

Available at http://www.cancerscreening.nhs.uk/screening-age-extension/rf.pdf

Condition
Breast cancer mortality

Intervention

Description of interventions as of 17/09/2013:

As part of the routine breast screening process, screening invitation batches are created typically containing several hundred women spanning ages 55 to 70 years. During the trial, batches include women aged 47 to 70 years. Each batch is randomly allocated to receive either the usual screening aged 60 or those aged 55-70 years. For women in the batch who are to be invited for screening, invitations will generally be sent out within several weeks of the batch being generated. New trial invitees in the batch will be randomly allocated to be invited to the trial as control.

Women aged 47-49 years in a batch where their age group is randomised not to be invited for screening may request to be screened. Women over 70 are already able to request screening every three years, irrespective of the trial.

The study will be monitored, analysed and reported as two entirely separate trials. One is a trial among younger women (randomly allocated at age 55-70) to additional screening invitation or control, the other is a trial among older women (randomly allocated at age 71-73) to additional screening invitation or control of the effects of an extra screening invitation among those who have had their final routine screening invitation.

Previous description of intervention:

As part of the routine breast screening process screening invitation batches are created of on average 1,000 women spanning ages 60 to 70 years. With the age extension, slightly larger batches of women aged 55 to 70 years will be created. Each batch will be randomly allocated to one of two groups, namely to receive either women aged 60-67 or women aged 55-70. Randomisation of the screening invitation batches will be done with equal probability and if stratification used, participants are the women aged 61-67 and 67-72 in these screening batches or, alternatively, there will be one third of 200 such women in each batch.

As a result of randomisation half of the women aged 47-49 and 71-73 will be invited for screening at this stage, while the other half will receive an invitation to screening as either women aged 55-70 or 60-67. Women aged 70, who are not invited for screening at this stage, will be invited to request screening every three years.

Intervention type:
Other

Phase:
Not Applicable

Drug names:

No medication.

Primary outcome measures:

Description of primary outcome measures as of 17/09/2013:
Breast cancer mortality

Previous description of primary outcome measures:

Mortality from breast cancer by age 65 for women invited to have an additional early screen (before age 60) versus those not invited and by age 90 for women invited to have an additional later screen (after age 70) versus those not invited

Secondary outcome measures:

Description of secondary outcome measures as of 17/09/2013:
1. Breast cancer incidence
2. Hospital admissions
3. Investigation, detection and treatment of breast lesions
4. Overall and cause specific mortality

Previous description of secondary outcome measures:
Eligibility

Participant inclusion criteria
1. Female
2. Aged 65 - 69 years or 70 - 73 years, and
3. In a Breast Screening Unit participating in the study. All Breast Screening Units in England are expected to participate in the study with the exception of those that use non-standard methods of imaging screening batches.

Participant type
Other

Age group
Adult

Gender
Female

Target number of participants
At least 500,000

Participant exclusion criteria
Does not meet inclusion criteria

Recruitment start date
01/06/2009

Recruitment end date
31/10/2012

Locations

Countries of recruitment
United Kingdom

Trial participating centre
Most breast screening units in England
via NHS Cancer Screening Programmes
Fulwood House Old Fulwood Road
Sheffield
S10 1TH
United Kingdom

Funders information
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Results and Publications

Publication and dissemination plan
Results will be disseminated in peer-reviewed open-access journals, at medical conferences and on the web. Datasets will be analyzed only in anonymized form, and publications will not identify individuals.

Intention to publish date

Participant level data
Not expected to be available

Results - basis reporting

Publication summary

Publication citations

Additional files

Editorial Notes