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Changing case Order to Optimise patterns of Performance in Screening (CO-OPS) Trial

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
11/05/2016

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In breast cancer screening, mammograms (x-ray images) are taken of womens breasts and examined for signs of cancer. In the NHS Breast Screening Programme each womans mammograms are examined separately by two radiologists, who each indicate if there should be recall for further tests. This is a highly skilled but repetitive activity where radiologists examine batches of 30-50 womens mammograms in each session. A decrease of performance has been observed over time in similar repetitive visual tasks, such as searching a radar screen for enemy aircraft. The current practice is for both radiologists to examine each batch of mammograms in the same order as one another, so their performance decrease would occur when looking at the same womens mammograms. We plan to run an experiment to test whether the two radiologists examining batches in a different order to one another increases the number of cancers detected. The idea is to make sure that optimal performance for the first and second radiologist happen when examining different womens mammograms, to improve overall cancer detection rates.

Who can participate?
Breast screening centres in England (UK).

What does the study involve?
In the intervention group, batches of mammograms will be presented to the two radiologists in the opposite order (one in appointment order and one in reverse appointment order). In the control group, the two radiologists will be presented with the mammograms in the same order. The main outcome will be whether there are more cancers detected in the intervention group than the control group.

What are the possible benefits and risks of participating?
The potential benefits are if the intervention is successful then it will result in fewer cancers being missed in the NHS breast screening programme. Participating centres will be sent a summary of results. The potential risk is that if successful the intervention will result in a larger number of disagreements and so a larger number of cases requiring arbitration review.

Where is the study run from?
University of Warwick (UK).

When is the study starting and how long is it expected to run for?
The study started in December 2012 and will run until September 2014.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Sian Taylor-Phillips
S.Taylor-Phillips@warwick.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13796

Study information

Scientific Title
Changing case Order to Optimise patterns of Performance in Screening (CO-OPS) randomised trial

Acronym
CO-OPS

Study objectives

We plan to run an experiment to test whether having two radiologists examine batches of mammograms in a different order to one another increases the number of cancers detected. The idea is to make sure that optimal performance for the first and second radiologist happen when examining different womens mammograms, to improve overall cancer detection rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee, First MREC approval date 27/06/2012, ref: 12/WM /0182

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

Interventions
Changing case order: Presenting batches of mammograms in the opposite order to the two readers (one in appointment order and one in reverse appointment order)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cancer detection rate; Timepoint(s): 1 year

Secondary outcome measures

1. Interval cancer rate; Timepoint(s): 3.5 years
2. Rate of disagreements between readers; Timepoint(s): 1 year
3. Recall rate; Timepoint(s): 1 year

Overall study start date
20/12/2012

Completion date
01/09/2014

Eligibility

Key inclusion criteria
The intervention is a change to breast screening centre systems. So recruitment is at the breast screening centre level. Inclusion criteria are that they are an NHS breast screening centre in England with at least one set of digital mammogrephy equipment used for screening. (The software intervention only works on digital equipment)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 44; UK Sample Size: 44

Key exclusion criteria
Exclusion criteria are centres who are outside of England, who are not part of the NHS breast screening programme, or do not have any digital mammography equipment.

Date of first enrolment
20/12/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
University House
Kirby Corner Road
Coventry
England
United Kingdom
CV4 8DS

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/01/2014		Yes	No
Results article	results	10/05/2016		Yes	No