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

Submission date 26/03/2013	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 26/03/2013	Overall study status Completed	 [_] Statistical analysis plan [X] Results
Last Edited 11/05/2016	Condition category Cancer	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

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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