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Can we use an artificial intelligence system to improve the quality and efficiency of breast cancer screening?

Submission date 15/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/06/2022	**Overall study status** Completed	
Last Edited 20/05/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
1 in 8 women will be diagnosed with breast cancer during their lifetime. Breast screening aims to find cancers early when treatment is more successful. In the UK breast screening programme, two cancer specialists (radiologists and radiographers) review the x-ray images (mammograms) taken during your visit. They decide if the mammogram is normal or whether further imaging or investigation is required. Any disagreements between the two specialists are reviewed further by a third specialist.

This research aims to test the ability of a new computer system developed by Google that uses a technology called artificial intelligence (AI) to help detect potential signs of cancer in the breast images (mammograms) that are taken during your screening visit. We have already completed a lot of research where we have shown that this technology is as good as an expert radiologist at identifying cancers on these scans. We believe that this technology has the potential to improve accuracy, safety, and patient experience of breast screening in the UK, and make the process more affordable for the NHS. It may also have a role in supporting NHS screening services and clinicians directly. We now need to understand how it works in a real-world NHS setting.

Who can participate?
Women aged 50 to 70 years old, undergoing routine breast cancer screening as part of the national breast screening programme at participating centres.

What does the study involve?
We will evaluate the performance of the AI system at Imperial College Healthcare NHS Trust and St. George's University Hospitals NHS Foundation Trust within the routine breast cancer screening in real time with no disruption or impact on screening appointment visits. This study only uses anonymised data to perform the study analysis. We will assess how the AI system can be integrated into the NHS screening pathway at Imperial College Healthcare NHS Trust and St. George's University Hospitals NHS Foundation Trust. We will test how quickly the AI can read the images and return results to the clinical site. Findings and lessons learnt from this study will help to design a screening pathway that may include AI as one of the readers.

Taking part in this study will not require any additional time, scans, or procedures, and will not affect your routine clinical care in any way. However, we hope that it may help others in the future.

What are the possible benefits and risks of participating?
We do not anticipate any disadvantages or risks to taking part. We do not anticipate any immediate benefits of taking part in this study. However, the information we get from this study will help us assess if artificial intelligence has the potential to improve future clinical care in the UK breast screening programme and worldwide, by providing more accurate reads, improving breast cancer detection, and by reducing the time to provide results to patients.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
May 2021 to August 2024

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

Who is the main contact?
Clinical Trial Manager, aimstrial@imperial.ac.uk

Study website
https://www.imperial.ac.uk/aiscreening

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307842

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 307842

Study information

Scientific Title
Artificial Intelligence in Mammography Study (AIMS) Part C - Feasibility of an artificial intelligence system to improve the quality and efficiency of breast cancer screening

Acronym
AIMS- Part C

Study objectives
A novel AI system for breast cancer screening to demonstrate read-only ‘silent’ integration of the AI system, in a non-interventional manner, at each participating site interfacing with the other technical systems used within the breast screening programme (NBSS and the Trust PACS), explicitly avoiding any potential for AI outputs to influence patient care.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 18/11/2022, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8115; Nottingham1.rec@hra.nhs.uk), ref: 22/EM/0198

Study design
Feasibility/pilot study

Primary study design
Observational

Secondary study design
Feasibility/pilot study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
https://www.imperial.ac.uk/aiscreening

Health condition(s) or problem(s) studied
Decision support in breast cancer screening

Interventions
Data will be collected prospectively from the breast screening programme (NBSS) Mammography Image Database, with patient consent. There will be no impact on patient care. The intervention is the AI system, assessed on de-identified prospective breast screening cases and outcomes. To understand how to perform technical integration of an artificial intelligence (AI) system into the standard clinical workflow.

Intervention Type
Other

Primary outcome measure
1. Time taken for the AI system to return results from mammograph images over the study dataset time period
2. Analysis of number of failure cases (such as such as model errors, software errors, integration errors, use errors, and hardware errors) for the study dataset time period. Accuracy will be measured as proportion of true results (both true positives and true negatives) among whole instances. Area under the receiver operating characteristic curve (ROC) will be measured for AI
3. Percentage of cases correctly excluded during eligibility checks and reasons do excursion during the study period

Secondary outcome measures
1. Accuracy measures including AI recall rate measured as proportion of true results (both true positives and true negatives)
2. AI sensitivity and specificity with respect to arbitrated recall decisions (measured as the number of positive cases (cases considered positive if they received a biopsy-confirmed diagnosis of cancer within 3 months following the screening visit. Negative cases will require a

negative result from the study screening visit)
3. AI sensitivity for biopsy-proven cancer u(true positive rate in percentage(%) derived by ROC analysis)
4. AI specificity for biopsy or diagnostic imaging-proven benign lesions (true negative rate in percentage (%) derived by ROC analysis)

Overall study start date
20/05/2021

Completion date
29/08/2024

Eligibility

Key inclusion criteria
1. Women undergoing routine breast cancer screening (age 50–70), as part of the national breast screening programme at Imperial College Healthcare NHS Trust and St George's University Hospital NHS Foundation Trust between the study dates.
2. Mammography images acquired using Hologic/Lorad, Siemens, or GE devices.

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Up to 14,000 participants

Total final enrolment
10875

Key exclusion criteria
1. Women that opt-out of this study
2. Women who have registered with the NHS national data opt-out

Date of first enrolment
27/11/2023

Date of final enrolment
28/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Teddington Memorial Hospital
Hampton Road
Teddington
United Kingdom
TW11 0JL

Study participating centre
Surbiton Health Centre
Ewell Road
Surbiton
United Kingdom
KT6 6EZ

Study participating centre
Edridge Road Community Health Centre
Impact House
2 Edridge Road
Croydon
United Kingdom
CR9 1PJ

Study participating centre
Robin Hood Lane Health Centre
Camden Road
Sutton
United Kingdom
SM1 2RJ

Study participating centre
Queen Mary's Hospital
Roehampton Lane
London

United Kingdom
SW15 5PN

Study participating centre
Purley War Memorial Hospital
856 Brighton Road
Purley
United Kingdom
CR8 2YL

Study participating centre
Charing Cross Hospital
Fulham Palace Road
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W6 8RF

Study participating centre
St Mary's Hospital
Praed Street
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United Kingdom
W2 1NY

Study participating centre
Ealing Hospital
Uxbridge Road
Southall
United Kingdom
UB1 3HW

Study participating centre
Heart of Hounslow
92 Bath Road
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United Kingdom
TW3 3LH

Study participating centre

Uxbridge Health Centre
George Street
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Sponsor type
University/education

Website
http://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Planned publication in a high-impact, peer-reviewed journal

Intention to publish date
21/03/2025

Individual participant data (IPD) sharing plan
Not expected to be made available due to contractual agreements with study sites

IPD sharing plan summary
Not expected to be made available