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Artificial intelligence in mammography study

Submission date	Recruitment status	[ ] Prospectively registered
25/05/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/06/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/06/2022	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
1 in 8 women will be diagnosed with breast cancer during their lifetime. It is a leading cause of cancer-related deaths among women worldwide. There is a need for rigorous large-scale studies to assess the performance of artificial intelligence (AI) for the diagnosis of breast cancer from breast scans (mammography). This should be done on diverse cohorts of women across multiple screening sites and on unenriched data representative of a true screening population. The aim of this study is to evaluate the performance of an AI system in detecting breast cancer on data representative of a true screening population.

Who can participate?
Being a retrospective study, no participants are directly involved in the study. There will be no effect or change to any participant's care.
Retrospective study (Part A): Historical data from women 50-70 years old who had a mammography as part of the national breast screening programme. The study will evaluate the AI system based on its analysis of historical, de-identified cases from study sites.
Arbitration study (Part B): Participants in the reader study will be voluntarily recruited from participating sites. Readers must be either breast screening radiologists or film reading radiographers.

What does the study involve?
Data will be collected from a mammography image database with patient consent. There will be no impact on patient care. The intervention is the AI system, assessed on de-identified retrospective breast screening cases and outcomes. The study will look at how specialists interact with the AI system in the arbitration clinic.

What are the possible benefits and risks of participating?
The researchers do not anticipate any disadvantages or risks to taking part. They do not anticipate any immediate benefits from taking part in this study. However, the information from this study will help to 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 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 May 2024

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

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

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
303782

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
21SM7312, IRAS 303782

Study information

Scientific Title
Clinical validation of an artificial intelligence system to improve the quality, efficiency and experience of breast cancer screening

Acronym

AIMS

Study objectives
A novel AI system for breast cancer screening demonstrates the appropriate accuracy, safety, acceptability, and cost-effectiveness required for use as an independent reader within the NHS breast screening programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/02/2022, 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/0038

Study design
Part A: retrospective diagnostic accuracy study; Part B: simulated usage of the AI system by readers in arbitration panels using retrospective data

Primary study design
Observational

Study type(s)
Screening

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

Interventions
Data will be collected retrospectively from the OPTIMAM Mammography Image Database, with patient consent. There will be no impact on patient care. The intervention is the AI system, assessed on de-identified retrospective breast screening cases and outcomes. To understand how the AI system would perform within a "double reading'' screening workflow, the study will look at how specialists interact with the AI system in the arbitration clinic.

Intervention Type
Other

Primary outcome(s)
Sensitivity and specificity of AI system cancer detection measured as the number of positive cases (cases considered positive if they received a biopsy-confirmed diagnosis of cancer within 39 months following the screening visit. Negative cases will require a negative result from the study screening visit, and another negative result at the subsequent screening visit at least 31 months later) compared to first, second and consensus reader decisions.

Key secondary outcome(s))
1. Case recall rate, cancer detection, positive predictive value, negative predictive value, cancer detection rate, area under the receiver operating characteristic curve will be measured for AI system performance over the study dataset time period
2. Subgroup performance by factors including cancer type and grade, primary tumour size, patient age, breast density, prior cancer, prevalent and incident screens, ethnicity, device

manufacturer, socioeconomic status, and screening site over the study dataset time period
3. Analysis of failure cases for the study dataset time period
4. Percentage of women that meet the eligibility criteria over the course of the study
5. Simulations of workforce impact assessment and health economic modelling over the study period
6. AI system localisation performance (if lesion position data available) over the study period
7. AI system performance in confirmed interval cancers (percentage of historical interval cancers that the AI system flagged for recall, and qualitative agreement of the localisation in the original screening mammogram with the presence/absence of true radiological evidence) over the study period

Completion date
21/05/2024

Eligibility

Key inclusion criteria
1. Women undergoing routine breast cancer screening (age 50-70 years) as part of the national breast screening programme from January 2016 onwards
2. Mammography images acquired using Hologic/Lorad, Siemens, or GE devices

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
70 years

Sex
Female

Key exclusion criteria
Part A:
1. Women attending an assessment clinic or symptomatic clinic (i.e. not routine screening)
2. Women undergoing annual screening due to:
2.1. High risk (lifetime risk >30% - e.g. faulty BRCA1, BRCA2, TP53)
2.2. Moderate risk (lifetime risk 17-30%)
2.3. Personal stratified follow up (e.g. indeterminate B3 lesions)
3. Presence of breast implants
4. Screens with incomplete (<4 standard screening views - e.g. due to abandoned screen)
5. Poor diagnostic quality imaging (which would be repeated)
6. Non-standard acquisitions beyond the routine 4 screening views

7. For negative or benign cases, women without a negative follow up screen approximately 3 years later (at least 31 months after initial screen), as this would preclude determination of a robust ground truth

Part B:
Same dataset as defined in Part A, with the same inclusion and exclusion criteria

Date of first enrolment
21/03/2022

Date of final enrolment
21/03/2024

Locations

Countries of recruitment
United Kingdom

England

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
London
United Kingdom
W6 8RF

Study participating centre
St Mary's Hospital
Praed Street
London
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
Hounslow
United Kingdom
TW3 3LH

Study participating centre
Uxbridge Health Centre
George Street
Uxbridge
United Kingdom
UB8 1UB

Sponsor information

Organisation
Imperial College London

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

Individual participant data (IPD) sharing plan
The data generated or analysed during the study cannot be shared at this time due to contractual agreements with study sites

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes