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A retrospective multi-centre clinical study of a deep learning system in identifying breast cancer through the assessment of mammograms

Submission date
10/01/2022

Recruitment status
No longer recruiting

Registration date
03/02/2022

Overall study status
Completed

Last Edited
11/02/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is a leading cause of cancer-related mortality among women worldwide, accounting for approximately 600,000 deaths annually.

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 a novel AI system in detecting breast cancer on diverse cohorts and unenriched data representative of a true screening population.

Who can participate?
Being a retrospective study, no participants are directly involved in the study, and there will be no effect or change to any participant's care. The study will evaluate the AI system based on its analysis of historical, de-identified cases from study sites where outcomes data (e.g. biopsy, histopathology results, follow-up information) is also collected.

What does the study involve?
Eligible cases will be presented to the AI system for analysis.

What are the possible benefits and risks of participating?
No benefits or risks of participating are anticipated.

Where is the study run from?
Kheiron Medical Technologies (UK)

When is the study starting and how long is it expected to run for?
March 2021 to December 2023

Who is funding the study?
The study is funded by an AI Award, awarded to Kheiron Medical Technologies, by the Accelerated Access Collaborative (AAC) in partnership with NHSX and the National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr. Annie Ng
annie@kheironmed.com

Contact information

Type(s)
Scientific

Contact name
Dr Annie Ng

Contact details
Kheiron Medical Technologies
2nd Floor, Stylus Building
112-116 Old Street
London
United Kingdom
EC1V 9BG
+44 (0)7379467701
annie@kheironmed.com

Type(s)
Scientific

Contact name
Dr Nisha Sharma

Contact details
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)1132433144
nisha.sharma2@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304086

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KMT004, IRAS 304086, CPMS 50959

Study information

Scientific Title
A retrospective multi-centre clinical study of a novel medical technology solution in the assessment of mammography images

Acronym
ARIES

Study objectives
The primary aim of this study is to evaluate the performance of Kheiron's software, Mia, in detecting malignancy to determine its effectiveness to serve as decision support in breast screening in a multi-centre setting.
Assessing the standalone behaviour of Mia characterises the contribution it could have as an independent reader in the overall double reading workflow. Assessing simulated double reading performance with Mia in various workflows enables the evaluation of Mia as an independent reader within various double reading configurations and workflows in breast screening.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Ethics approval not required as the research is limited to the use of previously collected, pseudonymised data.

Study design
Retrospective multi-centre clinical study of a CE marked medical device

Primary study design
Other

Secondary study design

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not applicable (study uses existing data)

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

Interventions
The intervention is the sponsor's deep learning software (Mia), assessed on de-identified randomised retrospective breast screening cases and outcomes. Comparison is made against the control arm of existing reference outcomes within the retrospective dataset where the deep learning software was not in use.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mia

Primary outcome measure
Sensitivity of the standalone case-wise malignancy detection performance of Mia, measured as the number of positive cases recalled divided by the total number of positive cases, over the full study dataset time period. Specificity of the standalone case-wise malignancy detection performance of Mia, measured as the number of confirmed negative cases not recalled divided by the total number of confirmed negative cases, over the full dataset time period.

Secondary outcome measures
Current secondary outcome measures as if 17/07/2023:

1. Measurement of relevant clinical metrics for Mia standalone and descriptives of cancer subtypes that Mia picks up to understand Mia’s contribution to double reading.
2. Comparison of Mia standalone and the historical first reader to understand differences in how their performance contributes to double reading.
3. Measurement of relevant clinical metrics, including resource/workload savings, and descriptives of cancer subtypes picked up in double reading workflows that incorporate Mia as an independent reader, to understand the performance of each workflow and to inform future health economic assessments.
4. Comparison of double reading workflows with and without Mia on clinically relevant metrics to understand differences in performance.
5. Comparison of double reading workflows with Mia against UK national guidelines to assess if guidelines thresholds would be met if Mia was used in double reading.
6. Secondary outcomes will also include performance stratified by region/site and ethnicity to confirm generalisability.

Previous secondary outcome measures:

1. Recall rate, negative flag rate, cancer detection rate, sensitivity, specificity, interval cancer rate, positive predictive value, percentage of interval cancers recalled, area under the receiver operating characteristic curve will be measured for Mia’s standalone performance over the study dataset time period and a selected one year period with the most complete data

2. Recall rate, cancer detection rate, sensitivity, specificity, interval cancer rate, positive predictive value, arbitration rate will be measured for various simulated double reading workflows with Mia over the study dataset time period and a selected one year period with the most complete data
3. Non-inferiority and superiority and associated absolute and relative differences between Mia standalone against the historical first reader will be measured for cancer detection rate, sensitivity, specificity, for either the study dataset time period or a selected one year period with the most complete data
4. Non-inferiority and superiority and associated absolute and relative differences between simulated double reading with Mia against historical double reading will be measured for cancer detection rate, sensitivity, specificity, recall rate, for either the study dataset time period or a selected one year period with the most complete data

Overall study start date
01/03/2021

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Female participants
2. Participants attending for breast screening purposes (normal and opportunistic screening)*
3. Participants for whom a 2D FFDM standard four-view mammography examination was acquired (MLO-R, CC-R, MLO-L, CC-L)
* Includes: 1) early recall cases (e.g. participants brought back for screening earlier than the established screening interval); and 2) participants of UK age extension trial (AgeX).

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Up to 1,000,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
31/01/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North London Breast Screening Programme (Royal Free London NHS Foundation Trust)
Pond Street
Hampstead
London
United Kingdom
NW3 2QG

Study participating centre
Gateshead Breast Screening Unit
Queen Elizabeth Hospital
Shrieff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
North East Devon Breast Screening Programme
Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Kheiron Medical Technologies (United Kingdom)

Sponsor details
2nd Floor, Stylus Building
112-116 Old Street
London
England

United Kingdom
EC1V 9BG
+44 (0)7599084908
annie@kheironmed.com

Sponsor type
Industry

Website
http://www.kheironmed.com

ROR
https://ror.org/01r3ct535

Funder(s)

Funder type
Government

Funder Name
Accelerated Access Collaborative (AAC) in partnership with NHSx and the National Institute for Health Research (NIHR)

Funder Name
Kheiron Medical Technologies

Results and Publications

Publication and dissemination plan
Peer reviewed publication is anticipated, alongside academic conference scientific presentations.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from science@kheironmed.com. Data will be shared according to a data-sharing plan.

IPD sharing plan summary
Available on request