ISRCTN78987039 https://doi.org/10.1186/ISRCTN78987039

Does triage of chest X-rays with artificial intelligence shorten the time to lung cancer diagnosis: a randomised controlled trial

Submission date 07/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/03/2023	**Overall study status** Ongoing	
Last Edited 28/02/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Diagnosing lung cancer early saves lives. Nearly three quarters of lung cancers are diagnosed late, at stage 3 or 4. One promising way to shorten the time to diagnose of lung cancer is to give patients their test results more quickly and proceed to the next step. Chest X-ray (CXR) and computed tomography (CT) scans are usually the first tests to suggest a diagnosis of lung cancer. Waiting for the results of a test is an anxious time for patients. If lung cancer is suspected, patients are often referred for a CT scan which may cause further anxiety. Usually, patients and their GPs do not receive these results straight away, and there can be longer delays due to the number of CXRs performed and imaging workforce shortages.

Immediate reporting allows patients to receive the result of the X-ray at the time of the test. If their X-ray is suspicious or unclear, patients are then offered a CT scan on the same day. CXRs for patients referred from primary care will be included, with help from the AI available for all patients. The study will test if AI helps identify CXRs from patients who will benefit most from same day CT, triaging for an immediate review and report at eight clinical sites over a 12 month period.

Who can participate?

This study requires all patients 18 years and over who have been referred by their GP for an AP or PA chest x-ray at the trial participating centres.

What does the study involve?

Patients will attend for their x-ray as normal and will receive the usual standard of care and referral pathways for each of the trial centres. Patients will not be asked to participate in any additional tests or assessments for the study. The AI will be randomised to intervention and non-intervention days and will highlight any possible abnormalities on chest x-rays. On non-intervention days the AI will be available later on, when being reviewed by radiologists. If a patient has an x-ray on an intervention day they may be asked to wait whilst the AI and radiographer check their results, and may be referred for a CT scan that same day, if possible.

What are the possible benefits and risks of participating?
Immediate reporting of GP chest X-rays has the potential to improve the patient experience by eliminating the wait for results, often an anxious time for patients. It may also streamline the diagnosis of lung cancer by performing additional radiology investigations (e.g. CT scan) at a single visit. This could reduce the time to diagnosis and minimise the number of patient attendances to hospital. It could also reduce the number of unnecessary urgent referrals to respiratory medicine, thus reducing patient anxiety. Given the nature of the study, we do not envisage any elevation to the harms or to the risk of harm for patients.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2022 to September 2025

Who is funding the study?
1. Clatterbridge Cancer Charity (UK)
2. NHS England (UK)

Who is the main contact?
Prof David Baldwin, David.baldwin12@nhs.net

Contact information

Type(s)
Scientific

Contact name
Prof David Baldwin

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
317009

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54991, SBRIC01P3039, IRAS 317009

Study information

Scientific Title
Impact of immediate AI enabled patient triage to chest CT on the lung cancer pathway

Acronym
LungIMPACT

Study objectives
Implementation of the AI will lead to a change in the timing of the CT scan for people with suspicious chest x-rays (CXR) and therefore to a change in the timing of the diagnosis of lung cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2023, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207104818; cambridgeeast.rec@hra.nhs.uk), ref: 23/EE/0014

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Lung cancer

Interventions

This is a prospective, multi-centre healthcare service delivery study with the primary objective of assessing the effectiveness of AI immediate read and worklist prioritisation for immediate review on the time to diagnosis of lung cancer and the time to CT chest following abnormal CXR. The study will be conducted over a 12-month period at eight NHS Trusts in England. qXR, a class IIa CE certified deep learning algorithm already in routine clinical use in some NHS Trusts, will be used in this study. All patients in the study will have their CXRs read by qXR. The only difference is the timing of the information from the AI. The process adopted in radiology departments is that the patient attends for a CXR and it is performed by a radiographer. The radiographer may, at their discretion flag abnormalities that may require further action and this may result in a CT scan being done, sometimes on the same day as is a preferred option in the NOLCP. Where there is no flag, the CXR is later reported by a radiologist or reporting radiographer. This study is testing whether having an AI immediate flag influences that process and shortens time to diagnosis.

AI clinical decision support will be available to the reporting practitioner (consultant radiologist, specialist registrar or reporting radiographer) for all CXRs. The intervention is the timing of the CXR alert from the AI, on intervention (worklist prioritisation for immediate report) and non-intervention (routine reporting time) days. On intervention days, an active notification will be sent to the worklist for any 'qXR-suspected-abnormal cases, so these can be prioritised for immediate reporting. Pre-allocation to intervention (qXR AI-immediate read and worklist prioritisation for immediate CXR review) and routine care (normal reporting with qXR read available) will occur using random sampling (Monday – Friday when routine imaging is performed). All patients over 18 years will have qXR decision support available. Patients will receive routine care, no additional diagnostic tests will be performed. Data will be collected from existing routine clinical data sources. All imaging (CXR or CT) will be performed as part of routine care, and no additional radiation exposure will be required. The reporting practitioner will have the AI decision support information for all cases and all days, the intervention is only the timing of the AI information (immediate reporting or with usual reporting). The reporting practitioner can choose to accept the alert and refer the patient for CT chest and/or referral onto the lung cancer pathway where appropriate. Patients who are referred for CT will follow the current CT and post-CT pathways of the participating clinical sites, which may include placing them on a cancer pathway. On non-notification days, the AI tool information will be available at the time the CXRs are reporting by the reporting practitioner. The PACS will have both the original image and qXR secondary capture showing the AI attention point.

Intervention Type
Other

Primary outcome measure
1. Time from chest X-ray to lung cancer diagnosis in days from the cancer waiting time database
2. Time from chest X-ray to CT (when performed) in days from the radiology information system

Secondary outcome measures
1. Time to first respiratory cancer outpatient appointment in days from the cancer waiting time database
2. Time to treatment start for lung cancer patients in days from the cancer waiting time database
3. Agreement between AI (qXR) and human readers for normal/abnormal interpretation of chest X-ray as an agree/disagree decision with discordance review by a thoracic radiologist where required
4. Number of urgent lung cancer referrals from the cancer waiting time database
5. The incidence of lung cancer from the cancer waiting time database

6. The stage of lung cancer diagnosis from the cancer waiting time database
7. Cost-effectiveness of AI support at the time of CXR acquisition and prioritisation for immediate review of CXRs; to be measured by difference in costs per patient diagnosed, per percentage increase in early-stage diagnosis and potentially per QALY subject to the availability of health utilities in the published studies

Overall study start date
01/02/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Chest X-ray referred from primary care
2. Age ≥18 years
3. Anteroposterior (AP) or Posteroanterior (PA) view

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150,000; UK Sample Size: 150,000

Key exclusion criteria
1. Age <18 years
2. CXR referral not from primary care
3. Lateral X-ray view of the chest

Date of first enrolment
01/08/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
United Lincolnshire Hospitals NHS Trust
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Mid Yorkshire Hospitals NHS Trust
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Aberford Road
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WF1 4DG

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
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LE1 5WW

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
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United Kingdom
B15 2GW

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
Colchester
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CO4 5JL

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Research & Innovation
Queens Medical Centre
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NG7 2UH
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Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name
Clatterbridge Cancer Charity

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from David Baldwin David.baldwin@nuh.nhs.uk - Fully anonymised clinical and outcome data will be available for 18 months after the end of the study and can be transferred digitally, upon request and with the correct data-sharing agreement.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.4	18/02/2023	07/03/2023	No	Yes
Protocol file	version 1.3	08/02/2023	20/03/2023	No	No
HRA research summary			26/07/2023	No	No