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A pre and post-study to compare the effect of AI-assisted radiology systems in detecting potentially cancerous lung nodules

Submission date 10/12/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/01/2025	**Overall study status** Ongoing	
Last Edited 21/01/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study aims to assess whether artificial intelligence (AI) can improve the detection of lung nodules and early-stage lung cancer when used to analyze chest X-rays. By comparing data from before and after AI deployment, the study will investigate if AI assistance identifies more lung nodules and if these nodules are cancerous or require further follow-up (such as CT scans or biopsies).

Who can participate?
Patients and healthy volunteers aged 35 years old and over who are obtaining chest X-rays at the site

What does the study involve?
The AI system, qXR-LN v4.0, will be integrated into the hospital's radiology workflow. In the pre-deployment phase, the information on number of nodules and lung cancers detected will be collected. In the post-deployment phase, AI assistance will notify radiologists of potential nodules, which they can review and confirm. This process will help evaluate the AI’s ability to detect nodules, and track cases of lung cancer diagnosed through AI chest X-ray.

What are the possible benefits and risks of participating?
For patients, there are no direct benefits or risks as this is an observational study, meaning no additional procedures or interventions are required. The AI system's involvement does not change the patients' usual care or treatment. The benefit lies in the potential for early detection of lung cancer in the future, as successful AI detection could lead to earlier and more accurate diagnoses. This study will be conducted at multiple hospitals, primarily in the Netherlands, and radiologists and clinical researchers will oversee the AI deployment and monitor results.

Where is the study run from?
Erasmus Medical Center, Netherlands

When is the study starting and how long is it expected to run for?
September 2023 to December 2026

Who is funding the study?
The study is supported by Qure.ai, the developer of the AI software qXR-LN.

Who is the main contact?
Dr. Jacob Visser (PI), j.j.visser@erasmusmc.nl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
qXR-LN-NL-001

Study information

Scientific Title
An ambispective pre and post-deployment observational cohort study to evaluate the yield of actionable lung nodules and lung cancer through chest X-rays using artificial intelligence

Acronym
APPEAL - AI

Study objectives

1. AI assistance can potentially help radiologists detect more lung nodule cases
2. AI assistance can potentially help in diagnosing more lung cancer cases
3. AI assistance can potentially help detect more early-stage lung cancer

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/09/2023, Medical Ethics Review Committee Erasmus MC (Postbus 2040, Rotterdam, 3000 CA, Netherlands; +31 107033625; metc@erasmusmc.nl), ref: MEC-2023-0534

This study will be conducted in the Netherlands and the AI to be used is ethically approved in this region. The participants' data is collected retrospectively, and no additional rules of conduct or actions are imposed on them, making this a non-Medical-Scientific Research with People Act (nWMO) project. The post-AI deployment is part of standard care, and the retrospective collection of data does not pose an extra burden on the patients nor does it require additional actions from them. As part of the nWMO approval decision, "exception informed consent" was granted. This study does not have any protocol-mandated procedure. The patients will be managed as per the treating physician’s judgement.

Study design
Multicentre ambispective pre- and post-deployment observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Detection of actionable lung nodules and lung cancer

Interventions
This is a pre-and post-deployment study. The study is observational at the patient level with no protocol-mandated procedures. A patient identified with a nodule will undergo management as per established guidelines which may include invasive procedures like biopsy or further imaging or follow-up which may extended up to two years. All patients receive the same standard of care in both periods.

The AI system, qXR-LN v4.0, will be integrated into the hospital's radiology workflow. In the pre-deployment phase, the information on number of nodules and lung cancers detected will be

collected. In the post-deployment phase, AI assistance will notify radiologists of potential nodules, which they can review and confirm. This process will help evaluate the AI's ability to detect nodules, and track cases of lung cancer diagnosed through AI chest X-ray.

Data collection takes place in two phases: a pre-deployment phase to establish baseline detection rates without AI, followed by a post-deployment phase with the AI in place. The total study duration is expected to span 2 years, with each phase involving data collection from around 100,000 patients.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Qure AI qXR LN v4.0 device; qXR AI-based chest X-ray reporting

Primary outcome measure
The following primary outcome measures are assessed using data collected from the Qure AI qXR LN v4.0 device:
1. Difference in actionable pulmonary nodule detection rate on chest X-rays between pre- and post-deployment periods
2. Difference in proportion of lung cancer cases diagnosed through nodule pathway between pre- and post-deployment periods

Secondary outcome measures
The difference in the proportion of early-stage lung cancer among all lung cancer between pre and post-deployment periods assessed using data collected from the Qure AI qXR LN v4.0 device

Overall study start date
19/09/2023

Completion date
15/12/2026

Eligibility

Key inclusion criteria
All participants above the age of 35 years obtaining chest X-rays at the site

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
35 Years

Sex
Both

Target number of participants
100000

Key exclusion criteria
Patients less than 35 years old and patients with known lung cancer at the time of chest X-ray

Date of first enrolment
09/01/2025

Date of final enrolment
09/01/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus University Medical Centre
Dr. Molewaterplein 40, 3015 GD Rotterdam, Netherlands
Rotterdam
Netherlands
3015 GD

Study participating centre
Catharina Ziekenhuis
Michelangelolaan 2, 5623 EJ Eindhoven, Netherlands
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Study participating centre
Maasstad Hospital
Maasstadweg 21, 3079 DZ Rotterdam, Netherlands
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Sponsor information

Organisation
Qure.ai Technologies Limited

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Qure.ai Technologies Limited

Results and Publications

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

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available due confidential nature of the data.

IPD sharing plan summary
Not expected to be made available