

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 No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name
Dr Jacob J. Visser

Contact details
Department of Radiology and Nuclear Medicine, Erasmus Medical Center, Dr. Molewaterplein 40
Rotterdam
Netherlands
3015
+31 0107030949
j.j.visser@erasmusmc.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

35 years

Sex

All

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
Netherlands
5623 EJ

Study participating centre**Maastad Hospital**

Maastadweg 21, 3079 DZ Rotterdam, Netherlands
Netherlands
3079 DZ

Sponsor information

Organisation

Qure.ai Technologies Limited

Funder(s)

Funder type

Industry

Funder Name

Qure.ai Technologies Limited

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study are not expected to be made available due to confidential nature of the data.

IPD sharing plan summary

Not expected to be made available