The impact of an AI tool on diagnostic accuracy, review time, and diagnostic confidence in detecting acute abnormalities in non-contrast CT head scans: a study among emergency medicine clinicians, general radiologists, and radiographers

Recruitment status No longer recruiting	Prospectively registered		
	[X] Protocol		
Overall study status	[X] Statistical analysis plan		
Completed	[X] Results		
Condition category	Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Background and study aims

The study aims to evaluate the impact of an AI tool called qER 2.0 EU on the diagnostic accuracy, speed, and confidence of healthcare professionals who review non-contrast CT head scans. The study will involve 30 readers, including general radiologists, emergency medicine clinicians, and CT radiographers, who will interpret 150 non-contrast CT head scans, first without and then with the assistance of the AI tool. The scans will include 60 control cases and 90 abnormal cases with intracranial haemorrhage, brain infarct, midline shift, or skull fracture. The study will assess the stand-alone performance of the AI tool and its impact on the readers' performance.

Who can participate?

Emergency medicine consultants and registrars, general radiologist consultants and registrars, and CT radiographers who review CT head scans as part of their clinical practice.

What does the study involve?

30 readers will be recruited across four NHS trusts including ten general radiologists, fifteen EM clinicians, and five CT radiographers of varying seniority. Readers will interpret each scan first without, then with, the assistance of the qER 2.0 EU AI tool, with an intervening 4-week washout period. Using a panel of neuroradiologists as ground truth, the stand-alone performance of qER will be assessed, and its impact on the readers' performance will be analysed as change in accuracy, mean review time per scan, and self-reported diagnostic confidence.

What are the possible benefits and risks of participating? None Where is the study run from?
Oxford University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for? October 2022 to October 2024

Who is funding the study?
This work was supported by the NHSX AI in Health and Care Award (UK)

Who is the main contact?

Prof. Alex Novak, alex.novak@ouh.nhs.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)

310995

ClinicalTrials.gov (NCT)

NCT06018545

Protocol serial number

IRAS 310995

Study information

Scientific Title

AI Assisted Reader Evaluation in Acute Computed Tomography (CT) head interpretation (AI-REACT)

Acronym

AI-REACT

Study objectives

The purpose of the study is to assess the impact of an Artificial Intelligence (AI) tool called qER 2.0 EU on the performance of readers, including general radiologists, emergency medicine clinicians, and radiographers, in interpreting non-contrast CT head scans. The study aims to evaluate the changes in accuracy, review time, and diagnostic confidence when using the AI tool. It also seeks to provide evidence on the diagnostic performance of the AI tool and its potential to improve efficiency and patient care in the context of the National Health Service (NHS). The study will use a dataset of 150 CT head scans, including both control cases and abnormal cases with specific abnormalities. The results of this study will inform larger follow-up studies in real-life Emergency Department (ED) settings.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/12/2022, Research Ethics Committee of the Central University (CUREC) and the Interdivisional Research Ethics Committee of Medical Sciences (IDREC) (Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 (6)16577; ethics@medsci.ox.ac.uk), ref: R80145/RE002

Study design

Observational cohort study that is retrospective multicenter and multireader

Primary study design

Observational

Study type(s)

Other, Efficacy

Health condition(s) or problem(s) studied

Extradural haemorrhage, Subdural haemorrhage, Subarachnoid haemorrhage, Intraparenchymal haemorrhage, Intraventricular haemorrhage, Brain infarct or stroke, Intracraneal Mass effect, Skull fractures

Interventions

A retrospective dataset of 150 non-contrast CT head scans will be compiled, to include 60 control cases and 90 abnormal cases with intracranial haemorrhage, brain infarct, midline shift or skull fracture. The intracranial haemorrhage cases will be sub-classified into extradural, subdural, subarachnoid, intraparenchymal, and intraventricular.

30 readers will be recruited across four NHS trusts including ten general radiologists, fifteen EM clinicians, and five CT radiographers of varying seniority. Readers will interpret each scan first without, then with, the assistance of the qER 2.0 EU AI tool, with an intervening 4-week washout period. Using a panel of neuroradiologists as ground truth, the stand-alone performance of qER will be assessed, and its impact on the readers' performance will be analysed as change in accuracy, mean review time per scan, and self-reported diagnostic confidence. Subgroup

analyses will be performed by reader professional group, reader seniority, pathological finding, and neuroradiologist-rated difficulty.

Intervention Type

Other

Primary outcome(s)

Reader and qER performance will be evaluated as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Area Under Receiver Operating Characteristic Curve (AUC). Reader performance will be evaluated with and without AI assistance. Reader speed will be evaluated as the mean review time per scan, with and without AI assistance.

Key secondary outcome(s))

Reader confidence will be evaluated as self-reported diagnostic confidence on a 10 point visual analogue scale, with 0 being not completely confident, and 10 being totally confident, evaluated with and without AI assistance.

Completion date

02/10/2024

Eligibility

Key inclusion criteria

Emergency medicine consultants and registrars, general radiologist consultants and registrars, and CT radiographers who review CT head scans as part of their clinical practice

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

30

Key exclusion criteria

- 1. Neuroradiologists
- 2. (Non-radiologist groups) Clinicians with previous formal postgraduate CT reporting training

3. (Emergency Medicine group) Clinicians with previous career in radiology/neurosurgery to registrar level

Date of first enrolment

27/06/2023

Date of final enrolment

04/08/2023

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital Headley Way Headington Oxford England OX3 9DU

Study participating centre Guy's and St Thomas' NHS Foundation Trust

St Thomas' Hospital Westminster Bridge Road London England SE1 7EH

Study participating centre

Northumbria Healthcare NHS Foundation Trust (headquarters)

Rake Lane North Shields England NE29 8NH

NHS Greater Glasgow and Clyde

J B Russell House Gartnavel Royal Hospital 1055 Great Western Road Glasgow Glasgow Scotland G12 0XH

Sponsor information

Organisation

Oxford University Hospitals NHS Trust

ROR

https://ror.org/03h2bh287

Funder(s)

Funder type

Government

Funder Name

NHS transformation directorate (NHSX)

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/02/2024	12/11/2025	Yes	No
Other unpublished results	version 0.1		12/11/2025	No	No
Other unpublished results	Supplementary materials version 2.4		12/11/2025	No	No
Participant information sheet	version 1.0	29/11/2022	12/09/2023	No	Yes

 Protocol file
 12/09/2023
 No
 No

 Statistical Analysis Plan
 version 0.1
 12/11/2025
 No
 No