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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

Submission date	Recruitment status	[_] Prospectively registered
07/09/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2023	Injury, Occupational Diseases, Poisoning	[_] Record updated in last year

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310995

ClinicalTrials.gov number
NCT06018545

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Other, Efficacy

Participant information sheet
See additional files

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2022

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
30

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
England

Scotland

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Northumbria Healthcare NHS Foundation Trust (headquarters)
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
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Sponsor information

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Oxford University Hospitals NHS Trust

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John Radcliffe Hospital
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Sponsor type
Hospital/treatment centre

Website
https://www.ouh.nhs.uk

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
NHS transformation directorate (NHSX)

Results and Publications

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

Intention to publish date
01/10/2025

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?
Participant information sheet	version 1.0	29/11/2022	12/09/2023	No	Yes
Protocol file			12/09/2023	No	No