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Medical utility of artificial intelligence for fracture detection in the emergency department

Submission date
07/11/2025

Recruitment status
No longer recruiting

Registration date
08/01/2026

Overall study status
Ongoing

Last Edited
25/08/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Broken bones (fractures) are commonly misdiagnosed in emergency departments, which can lead to patients experiencing delayed recovery, prolonged pain, and unnecessary follow-up visits to the NHS. In the UK, around 3.7 to 8.7% of suspected fractures are misdiagnosed, primarily because busy emergency staff incorrectly interpret X-rays. This can also lead to patients without fractures being incorrectly told they have a broken bone, resulting in unnecessary treatments. This study aims to test whether using artificial intelligence (AI) software to help clinicians identify fractures on X-rays can reduce these diagnostic errors and improve patient care. The AI tool automatically analyses X-ray images and highlights areas where fractures might be present, helping doctors and nurses make more accurate diagnoses.

Who can participate?
Anyone aged 2 years or older who attends an emergency department or minor injuries unit and has an X-ray taken for a suspected fracture can be included in this study. This includes both children and adults.
Patients cannot participate if they are under 2 years old, need X-rays for suspected child abuse, or require imaging of the skull, facial bones, teeth, or neck spine. Children under 18 with suspected lower back fractures are also excluded. Patients can opt out by using the national NHS data opt-out system or by completing an opt-out form displayed in the emergency department.

What does the study involve?
The study will run across several NHS hospitals and minor injuries units in the Thames Valley region. During the 6-month study period, AI software will be installed at each site. The AI tool will alternate between being switched on and off each month, so doctors sometimes have access to the AI assistance and sometimes do not.
Most patients will simply receive their normal emergency care. The study team will collect information from medical records to see whether the AI reduces misdiagnoses and unnecessary follow-up appointments. No additional X-rays or tests are needed.
A small number of patients (30 at each hospital) will be asked if they are willing to be contacted

one month after their visit to complete a short questionnaire about their experience. Staff at participating hospitals will also be invited to complete questionnaires about their experience using the AI tool.

What are the possible benefits and risks of participating?
The AI tool may help clinicians detect fractures more accurately, which could mean patients receive the right treatment more quickly and have fewer unnecessary follow-up visits. Patients might also experience less pain and recover more quickly if their fracture is correctly identified early on. For patients without fractures, there may be less chance of being incorrectly diagnosed and receiving unnecessary treatment.
The study involves minimal risk to patients. The AI software is a support tool only and does not replace the doctor's judgement. Clinicians will still make the final decision about diagnosis and treatment. The main risk is that the AI might occasionally make errors, but the study team will carefully monitor the tool's performance to ensure it is working safely. There are no physical risks as patients receive standard care with no additional procedures.

Where is the study run from?
The study is run from Oxford University Hospitals NHS Foundation Trust, with the main coordination happening at Headley Way, Oxford OX3 9DU.
The study will take place across four hospital trusts in the Thames Valley region:
1. Oxford University Hospitals (John Radcliffe Hospital and Horton General Hospital emergency departments)
2. Oxford Health NHS Foundation Trust (minor injuries units)
3. Royal Berkshire NHS Foundation Trust (Royal Berkshire Hospital emergency department and associated minor injuries units)
4. Buckinghamshire Healthcare NHS Trust (Stoke Mandeville Hospital emergency department and associated minor injuries units)

When is the study starting and how long is it expected to run for?
The study is expected to start in December 2025 and run until December 2026, lasting approximately 12 months in total. Patient recruitment will take place over a six-month period from December 2025 to July 2026.

Who is funding the study?
The study is funded by Radiobotics, the company that manufactures the AI fracture detection software being tested.

Who is the main contact?
Prof. Alex Novak, Alex.Novak@ouh.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Alex Novak

ORCID ID
https://orcid.org/0000-0002-5880-8235

Contact details
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 231550
Alex.Novak@ouh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
348658

Central Portfolio Management System (CPMS)
64480

Study information

Scientific Title
Systematic Assessment of the Medical Utility of Radiology Artificial Intelligence (SAMURAI) in Fracture Detection

Acronym
SAMURAI-Fracture

Study objectives
Primary Objective:
To evaluate whether implementation of an AI fracture detection tool reduces the proportion of patients having unnecessary NHS healthcare contacts as a result of incorrect diagnoses, i.e. false positive/negative conclusions.

Secondary Objectives:
To assess the technical performance of an AI fracture detection tool, and its impact on clinician experience, overall patient care experience and service provision.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 23/10/2025, UK Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8000; approvals@hra.nhs.uk), ref: 357391

2. Approved 23/10/2025, Joint Research Office, Oxford University Hospitals NHS Foundation Trust (Second Floor, OUH Cowley Unipart House Business Centre, Garsington Road, Oxford, OX4 2PG, United Kingdom; -; shahista.hussain@ouh.nhs.uk), ref: PID18979-SI001

3. Approved 23/10/2025, South Central – Oxford C Research Ethics Committee (Oxford University Hospitals NHS Foundation Trust Unipart House Business Centre, Garsington Road, Oxford, OX4 2PG, United Kingdom; -; oxfordc.rec@hra.nhs.uk), ref: 25/SC/0252

Primary study design
Interventional

Study design
Prospective cluster randomized cross over trial (ABAB/BABA)

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Patients undergoing X-ray for suspected fracture in the emergency department or minor injuries unit

Interventions
The trial will involve installing a MHRA- and CE-approved AI fracture detection software at each site for 6 months. Clinicians will be able to view AI annotated images to aid in diagnosis when reviewing X-rays for suspected fracture.

Sites will be randomly assigned to begin the trial with the AI algorithm either active ("On") or inactive ("Off") during the first month. Thereafter, the algorithm status will alternate each month (“AI On” and “AI Off”) for the remaining 5 months. This crossover design ensures that each site experiences both conditions multiple times, allowing within-site comparisons of outcomes under AI-assisted versus standard practice.

This study will be conducted across four sites, divided into three clusters:

Cluster 1:
Oxford University Hospitals NHS Foundation Trust:
John Radcliffe Hospital ED (Level 1 ED)
Horton General Hospital ED (Level 1 ED)
Oxford Health Trust:
MIUs (Level 3 EDs)

Cluster 2:
Royal Berkshire NHS Foundation Trust:
Royal Berkshire Hospital ED (Level 1 ED)
Associated MIUs (Level 3 ED)

Cluster 3:
Buckinghamshire Healthcare NHS Trust:
Stoke Mandeville Hospital ED (Level 1 ED)
Associated MIUs (Level 3 ED)

All patients undergoing an X-ray for suspected fracture will be eligible for the study. Dedicated research teams at each site will extract data from Electronic Patient Records and share the anonymised data with the central trial team for evaluation of primary and secondary outcomes. We will gather feedback from patients and clinical staff through electronic surveys at each site.

These sites will allow for sufficient patient heterogeneity (socioeconomic, geographical, population, ethnicity) as per the INCLUDE guidance to ensure that our results are generalisable to the wider UK population.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
RBFracture

Primary outcome(s)
Unnecessary NHS contacts measured via electronic patient record audit of composite endpoints (phone consultations, repeat ED attendances, additional imaging, GP consultations, late fracture clinic referrals, inappropriate early clinical use, unnecessary imaging, immobilization, and sick leave) compared between periods when AI system is active ("On") versus inactive ("Off") throughout the entire 6-month study period (December 2025 – May 2026), with comparison occurring monthly during the alternating On/Off periods.

Key secondary outcome(s)
Patient Impact:
1. False negative fracture detection rate measured by comparison of AI algorithm output versus final radiology report at each X-ray during AI "On" periods (December 2025 – May 2026)
2. False positive fracture detection rate measured by comparison of AI algorithm output versus final radiology report at each X-ray during AI "On" periods (December 2025 – May 2026)
3. Number of inappropriate interventions (unnecessary treatments/referrals) measured via electronic patient record audit comparing AI "On" versus AI "Off" periods throughout the 6-month study period
4. Patient-reported outcomes measured using the EQ-5D questionnaire at 1 month post-initial ED/MIU presentation (December 2025 – May 2026)

Clinician Impact:
1. Clinician satisfaction and confidence with the AI tool measured using a 5-point Likert scale questionnaire at baseline (December 2025) and 6 months (May 2026)

Service Impact:
1. Number of patients referred to Fracture Clinic from ED/MIU measured via electronic patient record and RIS audit comparing AI "On" versus AI "Off" periods throughout the 6-month study period
2. Number of patients admitted to hospital with suspected fractures measured via electronic patient record audit comparing AI "On" versus AI "Off" periods throughout the 6-month study period
3. Number of patients recalled to ED due to missed fractures (false negatives) measured via electronic patient record audit comparing AI "On" versus AI "Off" periods throughout the 6-month study period
4. Number of unplanned reattendances for the same injury measured via electronic patient record audit comparing AI "On" versus AI "Off" periods throughout the 6-month study period
5. Length of Stay (LoS) in ED/MIU for patients with suspected fractures (measured in minutes from registration to discharge) via electronic patient record audit comparing AI "On" versus AI "Off" periods at each patient visit throughout the 6-month study period

Technical Performance:
1. Sensitivity and specificity of the AI algorithm measured by comparison of algorithm output to

final radiology report as gold standard at each X-ray during AI "On" periods (December 2025 – May 2026)
2. Sensitivity and specificity by subgroup (anatomical region, fracture type, patient demographics, age, ethnicity, and comorbidities) measured by comparison of algorithm output to final radiology report by subgroup during AI "On" periods (December 2025 – May 2026)
3. Number of X-rays rejected or not processed by the AI algorithm (among those within intended use) measured via comparison of vendor algorithm processing logs versus hospital EPR/RIS imaging requests throughout the AI "On" periods (December 2025 – May 2026)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
All patients undergoing X-Rays in ED or MIU for a suspected fracture will be eligible for inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
2 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients under 2 years old
2. Skeletal survey conducted to assess for non-accidental injury
3. Skull, facial bone, dental, and cervical spine X-rays
4. Thoracolumbar spine X-rays in patients under 18 years old
5. Patient has opted out of data sharing on the National Data Opt-Out
6. Patient completes the opt out questionnaire displayed on posters in the waiting room

Date of first enrolment
24/02/2026

Date of final enrolment

30/07/2026

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
England
OX4 4XN

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Buckinghamshire Healthcare NHS Trust
Amersham Hospital
Whielden Street
Amersham
England
HP7 0JD

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Radiobotics

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request to Prof. Alex Novak, Chief Investigator, alex.novak@ouh.nhs.uk.
Type of data to be shared: Anonymised imaging data (X-ray images processed by RBFracture™ algorithm) and associated anonymised demographic, clinical, and outcome metadata
Timing of availability: Data will become available upon publication of the primary results manuscript, anticipated within 12 months of study completion
Duration of availability: Data will be made available for a minimum of 5 years post-publication
Access criteria and sharing mechanism: Access will be restricted to bona fide researchers undertaking research aligned with the study objectives. Requests will be reviewed by the study steering group. Data will be shared via secure transfer mechanisms compliant with UK GDPR and NHS information governance requirements
Participants' consent for data sharing: Participants were not explicitly consented to data sharing, however, the use of routine clinical data via EPR/RIS and an opt-out consent model supports secondary use for research aligned with the original study purpose
Data anonymisation: All data will be fully anonymised with the removal of identifiable information; re-identification will not be possible
Ethical and legal restrictions: Data sharing will comply with UK GDPR, NHS information governance protocols, and ethical approval conditions. No ethical restrictions are anticipated beyond these standard requirements
Additional comments: This dataset of ~45,000 fracture cases will support future post-market surveillance, algorithm validation studies, comparative evaluations of fracture-detection AI tools, and health economic analyses.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/08/2026	25/08/2026	Yes	No