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FRACT-AI: A study comparing the finding of broken bones on X-Rays by artificial intelligence to the findings by clinicians of varying grades and professional backgrounds

Submission date
17/11/2023

Recruitment status
No longer recruiting

Registration date
11/03/2024

Overall study status
Completed

Last Edited
06/09/2024

Condition category
Other

[_] 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
Some recent research has shown two things regarding how we look at x-rays to look for fractures, the first is that artificial intelligence (AI) shows that it can competently locate fractures, and the second is that in the emergency department, one of the most frequent problems is mistakes being made in locating fractures on x-rays.
This study brings those two things together, looking at how an AI performs in comparison to a human clinician, and further looks at how the human performs when helped by the AI. The human clinicians will represent several hospital professions (emergency medicine, orthopaedics, radiologists, radiology, physiotherapy and emergency nurses) and levels of experience ranging from junior staff to experienced consultant-level clinicians. The clinicians will look at 500 x-rays, of which half have a fracture, and half do not. The study will measure how many of them are correctly identified.

Who can participate?
Hospital professions (emergency medicine, orthopaedics, radiologists, radiology, physiotherapy and emergency nurses) in the trusts involved.

What does the study involve?
The study will begin recruitment at the start of September for eight weeks, with the first month of x-ray interpretation (where the participants don't have AI to help them) scheduled to begin on the 1st of November. After a period of time of one month (to reduce the chances of x-rays being remembered), the same x-rays will be looked at for a second time with the help of the AI.

What are the possible benefits and risks of participating?
There will be no risk to participants in this study. X-rays interpreted will be old x-rays that are not being used actively in the treatment of a patient.

Where is the study run from?
The study will occur over five NHS trusts in the Thames Deanery - Oxford University Hospitals, Royal Berkshire, Buckinghamshire Healthcare, Frimley Health and Milton Keynes University Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2022 to June 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Professor Alex Novak, alex.novak@ouh.nhs.uk
Doctor Sarim Ather, sarim.ather@ouh.nhs.uk

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Prof Alex Novak

ORCID ID
http://orcid.org/0009-0006-4086-3152

Contact details
John Radcliffe Hospital, Headley Way, Headington
Oxford
United Kingdom
OX3 9DU
0300 304 7777
alex.novak@ouh.nhs.uk

Type(s)
Scientific, Principal Investigator

Contact name
Dr Sarim Ather

ORCID ID
http://orcid.org/0000-0001-9614-5033

Contact details
John Radcliffe Hospital, Headley Way, Headington
Oxford
United Kingdom
OX3 9DU
0300 304 7777
sarim.ather@ouh.nhs.uk

Type(s)
Public

Contact name
Dr Max Hollowday

ORCID ID
http://orcid.org/0009-0001-0288-954X

Contact details
John Radcliffe Hospital, Headley Way, Headington
Oxford
United Kingdom
OX3 9DU
0300 304 7777
max.hollowday@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310995

ClinicalTrials.gov number
NCT06130397

Secondary identifying numbers
NIHR204982, IRAS 310995, CPMS 52221

Study information

Scientific Title
FRACT-AI: Evaluating the Impact of Artificial Intelligence-Enhanced Image Analysis on the Diagnostic Accuracy of Frontline Clinicians in the Detection of Fractures on Plain X-Ray

Acronym
FRACT-AI

Study objectives
Previous research has demonstrated AI's promising diagnostic performance in the location of fractures, and similarly X-Ray interpretation in the emergency department has been found to be a frequent source of error. These elements have not yet been compared in a UK clinical setting. This study hypothesises that artificial intelligence (Boneview) is more accurate at accurately locating fractures on plain X-Rays than that those interpreted by human clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/12/2022, UK Healthcare Research Authority (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8000; queries@hra.nhs.uk), ref: R80145/RE001

Study design
Multicentre multiple-reader multiple-case study

Primary study design
Observational

Secondary study design
Multiple-reader multiple-case study

Study setting(s)
Internet/virtual, Medical and other records

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Location of fractures on plain X-rays by artificial intelligence and human clinicians.

Interventions
The study broadly compares X-ray interpretation between human clinicians and an artificial intelligence designed to locate fractures in plain x-rays - Boneview.

500 plain x-rays will be interpreted by each participant, 50% pathological and 50% normal. The reference for the 50:50 divide will be set by a panel of specialised musculoskeletal radiologists, each x-ray being reviewed by at least two musculoskeletal radiologists to establish 'ground truth'. There will also be additional parameters ascribed to each x-ray, including the nature of the pathological finding, the location of the anatomy being investigated, and the difficulty of the image to interpret.

Plain x-rays not to be included are:
-X-ray Skull
-X-ray Cervical spine
-Postsurgical X-ray
-Follow-up x-ray for known fracture
-Paediatric x-ray (<18 years)

The human clinicians, hereafter termed 'readers', will show a range of specialities and levels of experience. 18 clinicians in total will be split evenly between 6 specialities: emergency medicine physicians, surgeons in trauma & orthopaedics, radiologists, radiographers, physiotherapists, and finally emergency nurse practitioners (nurses specialising in minor trauma injuries in the emergency department). Within these groups, consisting of 3 clinicians each, there will be a person of consultant/equivalent level (>10 years' practice), registrar/equivalent (5-10 years' practice), and senior house officer/equivalent (>5 years' practice).

The images will be run through Boneview. The readers will then interpret the same set of randomised images twice, once without the aid of Boneview, and after a washout period of no less than a month, a second time with the assistance of Boneview.

The study will therefore compare AI on its own with unassisted readers, and with AI and readers working in synchrony. As a subset, data will also be collected on the professional background of the reader, and their level of experience.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gleamer Boneview

Primary outcome measure
Clinician readers will be asked to identify the presence or absence of fracture by placing a marker on the image at the location of the fracture (if present) and to rank their confidence for fracture identification. Confidence rating will take the form of a Likert scale from 1 to 10, 1 being least confident, 10 being very confident).

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
13/12/2022

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Healthcare professional from the following professions/specialities:
1.1. Emergency medicine physicians
1.2. Surgeons in trauma and orthopaedics
1.3. Radiologists
1.4. Radiographers
1.5. Physiotherapists
1.6. Emergency nurse practitioners

Participant type(s)
Health professional

Age group

Adult

Sex
Both

Target number of participants
18

Total final enrolment
16

Key exclusion criteria
1. Not from the above listed professions (emergency medicine physicians, surgeons in trauma and orthopaedics, radiologists, radiographers, physiotherapists, emergency nurse practitioners.)
2. Radiologists already musculoskeletal specialists,

Date of first enrolment
01/09/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

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
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

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

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Sponsor information

Organisation
NIHR Clinical Research Network

Sponsor details
Old Rd, Headington
Oxford
England
United Kingdom
OX3 7LD
+44 1865 226764
enquiries@nihr.ac.uk

Sponsor type
Government

Website
https://www.crn.nihr.ac.uk/

ROR
https://ror.org/05fj7ar22

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in mind for this study are the British Medical Journal and the Emergency Medicine Journal

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2		01/12/2023	No	Yes
Protocol file	version 0.7		01/12/2023	No	No

Protocol article	05/09/2024	06/09/2024	Yes	No