# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
17/11/2023		[X] Protocol			
Registration date	Overall study status Completed  Condition category Other	Statistical analysis plan			
11/03/2024		Results			
Last Edited		Individual participant data			
06/09/2024		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
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# **Contact information**

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#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### **Integrated Research Application System (IRAS)**

310995

#### ClinicalTrials.gov (NCT)

NCT06130397

#### Protocol serial number

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 Al'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

#### Study type(s)

Diagnostic

#### 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

#### **Phase**

Not Applicable

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

Gleamer Boneview

#### Primary outcome(s)

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).

#### Key secondary outcome(s))

There are no secondary outcome measures

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

### 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

#### **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**

#### 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?
<u>Protocol article</u>		05/09/2024	06/09/2024	Yes	No
Participant information sheet	version 0.2		01/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.7		01/12/2023	No	No