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Testing an artificial intelligence tool for childhood fracture detection on X-rays

Submission date	Recruitment status	[_] Prospectively registered
10/11/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/08/2024	Musculoskeletal Diseases	[X] 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 BoneView (provided by vendor: Gleamer) on the diagnostic accuracy, confidence and potential change in management plans of healthcare professionals who routinely review bone radiographs of children. The study will involve a minimum of 40 readers, including general radiologists, emergency medicine clinicians, reporting radiographers and orthopaedic surgeons who will interpret 500 paediatric limb radiographs (across 4 body parts - ankle, wrist, elbow, knee) without and with the assistance of the AI tool. The scans will include approximately 35% abnormal (fractured) cases and the rest normal to simulate the normal prevalence of injuries in clinical practice. The study will assess the stand-alone performance of the AI tool and its impact on the readers' performance.

Who can participate?
Radiologists, emergency medicine, orthopaedic surgical consultants and registrars, reporting radiographers and senior triage nurses who review paediatric limb radiographs as part of their clinical practice.

What does the study involve?
40 readers will be recruited as stated above. Readers will interpret each of the 500 paediatric radiographs both without and with AI assistance (BoneView tool). Each reader will provide an opinion on presence/absence of fracture (and location of fracture where relevant), confidence score (scale of 1 to 5, 5 = very confident) and their management plan (based on a drop down menu checklist, tailored for each specialty type).

Using a panel of two consultant radiologists as setting the ground truth, the stand-alone performance of BoneView will be assessed, and its impact on the readers’ performance will be analysed as change in accuracy and changes in self-reported diagnostic confidence.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to August 2026

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

Who is the main contact?
Dr. Susan Shelmerdine, susan.shelmerdine@gosh.nhs.uk

Study website
https://www.fracturestudy.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274278

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 274278

Study information

Scientific Title
External validation of an artificial intelligence tool for paediatric fracture detection

Acronym
FRACTURE Study

Study objectives
A commercially available AI algorithm can be used for accurate paediatric fracture detection, and potentially improve clinical decision making in a simulated implementation study.

Ethics approval required
Ethics approval not required

Ethics approval(s)
HRA approval has already been granted and REC approval waived for the collection of the retrospective multicentric dataset. Ethical approval is not required for the multi-reader case study of healthcare professionals

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)
Diagnostic, Safety, Efficacy

Participant information sheet
Not applicable (retrospective study)

Health condition(s) or problem(s) studied
Acute fractures in otherwise healthy children (i.e. no underlying skeletal dysplasia, metabolic bone disease)

Interventions
Current interventions as of 30/08/2024:
A retrospective dataset of 500 scans will be compiled, to include fractures across 4 body parts in children (older than 2 years old, but less than 16 years old; both genders). The body parts include ankles, wrists, elbows and knees. There will therefore be 125 scans per 4 body parts, with each body part being approximately 35% abnormal (i.e. each body part = 81 normal and 44 abnormal (fractured)). This balance of normal to abnormal is intended to better mimic clinical practice whilst still being statistically powered.

40 readers will be recruited across all NHS sites to include at least 6 radiologists (both general, paediatric and musculoskeletal radiologists – of any experience level), 6 reporting radiographers, 6 emergency department staff (i.e. physicians), 6 senior triage nurses and 6 orthopaedic surgeons - each group comprising of staff of varying seniority.

Readers will interpret each of the 500 scans twice in a random order during two different reading sessions i.e. the first without AI assistance, and the second with AI assistance. The image viewer platform will randomise the order of the studies so that each reader at each session will be viewing the images in completely random order by abnormality and body part. There will be a washout period of 4 weeks in between the two reading sessions to minimise reader memory of the radiographs reviewed

The ground truth (reference standard) will be set by two consultant paediatric radiologists. The stand-alone performance of BoneView will be assessed, and its impact on the readers' performance will be analysed as changes in accuracy, self-reported diagnostic confidence and changes in diagnostic decision-making.

Subgroup analyses will be performed by the reader professional group and reader seniority. Inter- and intra-observer variability will be evaluated.

Previous interventions:
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Intervention Type
Other

Primary outcome measure
Reader and AI performance of the paediatric X-rays will be evaluated using measures of sensitivity, specificity, positive predictive value, negative predictive value and accuracy, where each correctly identified fracture on an Xray (where one exists) will be counted as a true positive, and each incorrectly identified fracture on an Xray (i.e. an overcall) will be counted as a false positive. Where fractures are present but not identified by the reader, this will constitute a

false negative. Where no fracture exists, and none is identified by the reader, this will count as a true negative.

The performance measures listed above will be compared for each reader before and after using AI assistance in interpretation of the X-rays. The performance of the AI tool alone will also be evaluated (without a human in the loop) for comparative measure.

Secondary outcome measures
1. The reader confidence in their diagnostic ability to identify or confirm the absence of a fracture per Xray will be measured using a survey provided at the time of reviewing each Xray on the image viewer platform using a 5 point Likert scale (1 = not confident, 5 = very confident). Differences will be compared in these scores before and after the use of the AI tool.
2. The readers' intended management plan (for the patient) based on the Xray will be provided in a drop down menu (7 options available) provided on the image viewer platform next to each Xray the reader has to interpret. The reader will need to select the single best option they would follow. The differences in theoretical management choices will be compared before and after the use of the AI tool.

Overall study start date
01/09/2021

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Radiographic 'readers' will include radiology consultants and registrars (either general, musculoskeletal or paediatric subspecialty interests), emergency medicine consultants and registrars, orthopaedic surgical consultants and registrars and reporting radiographers who review paediatric limb radiographs 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
40

Key exclusion criteria
Any doctor, nurse, radiographer who does not routinely review paediatric radiographs in their clinical practice or for their job.

Date of first enrolment
01/12/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
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WC1N 3JH

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
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SW17 0QT

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
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SE5 9RS

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
Great Ormond Street, London
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United Kingdom
WC1N 3JH
+44 2079052700
research.governance@gosh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

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 publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

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?
Protocol file	version 1.4	26/12/2023	28/12/2023	No	No