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Testing an artificial intelligence algorithm for detecting newborn hip dysplasia on ultrasound scans

Submission date	Recruitment status	[ ] Prospectively registered
18/06/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/06/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/06/2024	Neonatal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to evaluate the impact of an AI algorithm on the diagnostic accuracy, speed and confidence of healthcare professionals in diagnosing developmental dysplasia of the hip (DDH) on ultrasound scans. The study will involve 10 readers, who will interpret 70 ultrasound scans of baby hips, with and without AI assistance. The scans will include 35 normal and 35 abnormal cases, all of which have been obtained during routine screening in the NHS. The study will also assess the stand-alone performance of the AI algorithm.

Who can participate?
Consultants/attendings (specialising in Paediatric Orthopaedic Surgery) and registrars/residents. Specialist physiotherapists who take part in hip screening as part of their clinical practice.

What does the study involve?
10 readers of varying seniority will be recruited from eight NHS Trusts. This will include five consultant/attending surgeons, four registrars/residents and one specialist physiotherapist. Readers will interpret each scan with and without AI assistance, with an intervening 2-week "washout" period. Each reader will mark seven anatomical points (landmarks, used to determine the diagnosis) in each scan. They will provide their overall confidence score (scale of 1 to 5, 1 = not confident, 5 = very confident) in annotating all the points apart from the labrum.
Using a panel of two paediatric orthopaedic surgeons who specialise in DDH as ground truth, the stand-alone performance of the AI algorithm will assessed, alongside its impact on reader's accuracy, mean review time per scan and self-reported diagnostic confidence.

What are the possible benefits and risks of participating?
The results may show the utility of the AI algorithm as an assistive diagnostic tool. There are no risks of participating.

Where is the study run from?
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2024 to January 2025

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

Who is the main contact?
Mr Abhinav Singh, Abhinav.singh@ndorms.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
316325

Study information

Scientific Title
Developing and testing computer-assisted diagnostic tools for screening of developmental dysplasia of the hip in newborns: a multi-reader multi-case study

Acronym
DeTeCT DDH

Study objectives
An assistive AI algorithm can improve the diagnostic accuracy, speed and self-reported confidence of clinicians in diagnosing developmental dysplasia of the hip (DDH) on ultrasound scans.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Approved 14/03/2023, Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048000; approvals@hra.nhs.uk), ref: 23/HRA/0966

REC approval was waived for the collection of a retrospective fully anonymised dataset. Ethical approval is not required for the multi-reader multi-case study of healthcare professionals.

Primary study design
Observational

Study design
Retrospective multicentre and multireader observational cohort study

Study type(s)
Diagnostic, Safety, Efficacy

Health condition(s) or problem(s) studied
Developmental dysplasia of the hip in newborns, diagnosed by ultrasound scan

Interventions
A retrospective dataset of 70 newborn ultrasound scans will be compiled to include 35 normal and 35 abnormal (dysplastic [25]/dislocated [10]) hips. The case balance is intended to better mimic clinical practice whilst still being statistically powered to detect a suspected difference in accuracy.

10 readers of varying seniority will be recruited from eight NHS Trusts. This will include five consultant/attending orthopaedic surgeons, four orthopaedic registrars/residents and one specialist physiotherapist. Readers will interpret each scan with and without AI assistance in two different sessions. There will be an intervening 2-week "washout" period to minimise reader memory of the reviewed scans.

Each reader will mark seven anatomical points (landmarks) used to determine the diagnosis on each scan. They will provide their overall confidence score (scale of 1 to 5, 1= not confident, 5= very confident) in annotating all the points apart from the labrum. Using a panel of two paediatric orthopaedic surgeons who specialise in DDH as ground truth (reference standard), the stand-alone performance of the AI algorithm will assessed, alongside its impact on the reader’s accuracy, mean review time per scan and self-reported diagnostic confidence. Subgroup analysis will be performed by the seniority of the reader.

Intervention Type
Other

Primary outcome(s)
Reader and AI algorithm performance will be evaluated as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and Area Under Receiver Operating Characteristic Curve (AUC). Where the hip is abnormal on the ultrasound and readers correctly identify this classification as abnormal, it will be counted as a true positive, an incorrect diagnosis of normal by the reader will be a false negative. Where the hip is normal on the

ultrasound, its correct classification by the reader will be a true negative and an incorrect classification will be a false positive.

The performance measures listed above will be compared for each reader with and without AI assistance. The performance of the AI algorithm alone will also be evaluated as a comparative measure.

Key secondary outcome(s)
Reader speed will be evaluated as the mean review time per scan, with and without AI assistance. Reader confidence will be evaluated via a self-reported score (scale of 1 to 5, 1= not confident to 5 = fully confident), with and without AI assistance.

Completion date
31/01/2025

Eligibility

Key inclusion criteria
Consultants/attendings (specialising in Paediatric Orthopaedic Surgery) and registrars/residents. Specialist physiotherapists who take part in hip screening as part of their clinical practice.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
10

Key exclusion criteria
Any healthcare professional who does not review newborn hip ultrasound scans (either autonomously or under direct supervision) in their clinical practice

Date of first enrolment
01/03/2024

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
Botnar Research Centre
Old Road
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OX3 7LD

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
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SO16 6YD

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Colney Lane
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NR4 7UY

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SW17 0QT

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
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HA7 4LP

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
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Study participating centre
Imperial College Heathcare NHS Trust
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South Wharf Road
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W2 1NY

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
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SM5 1AA

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
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Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

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

Funder Name
InnovateUK

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
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