ISRCTN49436239 https://doi.org/10.1186/ISRCTN49436239

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

Contact name
Mr Abhinav Singh

ORCID ID
https://orcid.org/0000-0002-7329-6792

Contact details
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Research Centre
Old Road
Oxford
United Kingdom
OX3 7LD
+44 (0)1865227374
Abhinav.singh@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316325

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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.

Study design
Retrospective multicentre and multireader observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records, University/medical school/dental school

Study type(s)
Diagnostic, Safety, Efficacy

Participant information sheet
Not applicable

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/02/2024

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

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
England

United Kingdom

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

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

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

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

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
United Kingdom
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
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Imperial College Heathcare NHS Trust
The Bays
South Wharf Road

London
United Kingdom
W2 1NY

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

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

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics & Assurance
Boundary Brook House
Churchill Drive
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865616480
RGEA.Sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

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