ISRCTN33985096 https://doi.org/10.1186/ISRCTN33985096

Assessing AI-enhanced portable ultrasound screening for infant hip dysplasia

Submission date
11/07/2024

Recruitment status
Recruiting

Registration date
23/07/2024

Overall study status
Ongoing

Last Edited
23/07/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
About 1% of children are born with a loose, abnormally shaped hip joint, known as a dysplastic hip. Early detection in infancy allows for successful treatment with a harness or brace. If missed, there is a high risk of developing early osteoarthritis. Current clinical tests for hip dysplasia primarily detect severe cases, and traditional ultrasound screening has several limitations: it can be overly sensitive to minor shape changes, measurements on images are unreliable, and it is challenging for technicians to perform on squirming infants.
Early tests indicate that the 3D shape of the hip joint can be easily scanned using the same 3D ultrasound probe commonly used for fetal scans. These 3D images allow for optimal viewing angles without relying on the technician’s skill. 3D sequences are now included in some routine scans in Edmonton, and pseudo-3D models can also be created from video 'sweep' images recorded during conventional 2D ultrasound scans.
3D hip models are being developed based on existing ultrasound data. This study aims to further test and develop 3D hip ultrasound by determining the severity of hip dysplasia (if any) at each child's first visit, and by following each child's hip development and outcomes over several years. The researchers believe the 3D method will be easier to use at the bedside, measure hips more accurately, and provide valuable information about abnormal hip shapes. They are also testing artificial intelligence (AI) to automatically detect abnormal hips from 3D ultrasound or 2D "sweep" images. If successful, these methods could be applied to handheld portable ultrasound devices used by lightly trained personnel, such as primary care clinic nurses, potentially enabling widespread DDH screening.

Who can participate?
Infants aged from newborn to 12 weeks born in Alberta attending wellness checks (around 6-8 weeks) at participating sites

What does the study involve?
Each participant will undergo an initial 3D ultrasound scan to screen for hip dysplasia. Follow-up assessments will be conducted at regular intervals over a 5-year period to monitor hip development and clinical outcomes. All assessments involve non-invasive ultrasound imaging and clinical evaluations.

What are the possible benefits and risks of participating?
The potential benefits include more accurate and reliable detection of hip dysplasia, which can lead to early and effective treatment. There are minimal risks associated with the study as it involves non-invasive ultrasound imaging.

Where is the study run from?
University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
July 2012 to December 2032

Who is funding the study?
1. Arthritis Society Canada (Canada)
2. TD Better Health Program (Canada)
3. Women and Children's Health Research Institute (WCHRI) (Canada)
4. Alberta Machine Intelligence Institute (AMII) (Canada)

Who is the main contact?
Dr Jacob Jaremko, jjaremko@ualberta.ca

Study website
https://arthritis.ca/living-well/2024/catching-and-correcting-hip-dysplasia-as-quickly-as-possible

Contact information

Type(s)
Principal Investigator

Contact name
Dr Jacob Jaremko

ORCID ID
http://orcid.org/0000-0001-5314-2297

Contact details
8303 112 St NW
Edmonton
Canada
T6G 2T4
+1 (0)780 493 2773
jjaremko@ualberta.ca

Type(s)
Scientific

Contact name
Dr Abhilash Hareendranathan

ORCID ID
http://orcid.org/0000-0001-6201-9258

Contact details
8303 112 St NW
Edmonton
Canada
T6G 2T4
+1 (0)780 493 2773
hareendr@ualberta.ca

Type(s)
Public

Contact name
Dr Cassandra Gallant

Contact details
8303 112 St NW
Edmonton
Canada
T6G 2T4
+1 (0)780 493 2773
cgallan1@ualberta.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessment of developmental dysplasia of the hip screening in infants by AI-enhanced 3D point-of-care ultrasound: correlation with clinical and imaging findings at initial infant screening and follow-up

Study objectives
Three-dimensional (3D) ultrasound, either obtained with 3D probe or by cine sweep with conventional 2D probe, enhanced with artificial intelligence (AI), could improve the accuracy and reliability of developmental dysplasia of the hip (DDH) screening in infants, compared to current single-image two-dimensional (2D) ultrasound methods, by providing more comprehensive imaging and enabling automated diagnosis even when performed by minimally trained personnel.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/10/2012, University of Alberta Health Research Ethics Board (116 St & 85 Ave, Edmonton, T6G 2R3, Canada; +1 (0)780 492 3111; reoffice@ualberta.ca), ref: MS23_Pro00032107

The University of Alberta Human Research Ethics Board granted a waiver of consent for this project, given that ultrasound is a harmless imaging modality, but the researchers still included a brief assent discussion with each family prior to performing scans.

Study design
Multicenter prospective longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community, GP practice, Hospital

Study type(s)
Diagnostic, Prevention, Screening, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Diagnostic screening for developmental dysplasia of the hip (DDH) in infants

Interventions
Participants undergo initial screening for developmental dysplasia of the hip (DDH) using AI-enhanced 3D ultrasound (by 3D probe and/or cine sweep) at well-baby checkups (6-10 weeks old). All data collection is non-invasive, with ultrasound imaging and clinical evaluations conducted during routine pediatric visits.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Exo Iris (Exo Inc., Santa Clara, CA, USA)

Primary outcome measure
Diagnostic accuracy of DDH screening (using the US/AI model) against gold-standard conventional clinical ultrasound diagnosis, as assessed by sensitivity, specificity, positive and negative predictive value and AUC at the time of baseline ultrasound

Secondary outcome measures
1. Implementation success, assessed using the Consolidated Framework for Implementation Research (CFIR) 5-point framework, measured starting at initial rollout (2021), and every 3 years thereafter until the conclusion of recruitment (2024, 2027, 2030)
2. Feasibility of DDH screening (using the US/AI model) in neonates vs conventional physical assessments conducted by a physician at baseline, assessed by.System Usability Score (SUS), qualitative analysis of user and patient/family feedback from semi-structured interviews, and economic analysis. This is assessed every 3 years as above, based on data collected continuously and reviewed annually.

Overall study start date
01/07/2012

Completion date
31/12/2032

Eligibility

Key inclusion criteria
1. All infants in Alberta that can be reached with the technology
2. Age range from newborn to 12 weeks

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
0 Days

Upper age limit
24 Weeks

Sex
Both

Target number of participants
20,000

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/01/2020

Date of final enrolment
31/12/2030

Locations

Countries of recruitment
Canada

Study participating centre
Westland Family Practice
#240 70 McLeod Ave
Spruce Grove
Canada
T7X 3C7

Study participating centre
Westgrove Clinic
#201 505 Queen St
Spruce Grove
Canada
T7X 2V2

Study participating centre
Saint Mary Family & Walk-In Clinic
#1101 2827 30 Ave
Red Deer
Canada
T4R 2P7

Study participating centre
Fort McMurray Community Health Services
113 Thickwood Blvd
Fort McMurray
Canada
T9H 3S5

Study participating centre
Wetaskiwin Hospital and Care Centre
6910 47 St
Wetaskiwin

Canada
T9A 3N3

Study participating centre
Maskwacis Health Services
Minde Ave & Wolfe St, 14 Ermineskin Ave
Maskwacis
Canada
T0C 1N0

Study participating centre
Siksika Health Services
547 Highway 901
Siksika
Canada
T0J 3W0

Study participating centre
Red Deer Regional Hospital Centre
3942 50a Ave
Red Deer
Canada
T4N 4E7

Study participating centre
Stollery Surgical Clinic - University of Alberta Hospital
8440 112 St NW
Edmonton
Canada
T6G 2B7

Sponsor information

Organisation
University of Alberta

Sponsor details
2-13 Heritage Medical Research Centre
Edmonton

Canada
T6G 2R7
+1 (0)780 918 0654
robin.love@ualberta.ca

Sponsor type
University/education

Website
http://ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Charity

Funder Name
Arthritis Society

Alternative Name(s)
Société de l’arthrite

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Funder Name
TD Bank

Alternative Name(s)
TD Bank, N.A.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Women and Children's Health Research Institute

Alternative Name(s)
Women & Children's Health Research Institute, WCHRI

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Funder Name
Alberta Machine Intelligence Institute

Alternative Name(s)
AMII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals, including Implementation Science, Pediatric Imaging, Bone & Joint, Computers in Biology and Medicine, Journal of Ultrasound, and Journal of Pediatric Orthopaedics.
Planned dissemination into high-impact conferences, including the Pediatric Orthopaedic Society of North America (POSNA), the International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI), and the Radiological Society of North America

(RSNA).
Further dissemination will include sharing reported outcomes of DDH screening using the US/AI tool with Alberta Health Services (AHS).

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the conditions imposed by our data transfer agreements. Additional information related to the data and analysis are available from the corresponding author on reasonable request.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/07/2024	No	Yes