# Assessing AI-enhanced portable ultrasound screening for infant hip dysplasia

Submission date	Recruitment status Recruiting	<ul><li>Prospectively registered</li></ul>		
11/07/2024		☐ Protocol		
Registration date 23/07/2024	Overall study status Ongoing  Condition category Musculoskeletal Diseases	Statistical analysis plan		
		Results		
Last Edited		Individual participant data		
23/07/2024		<ul><li>Record updated in last year</li></ul>		

#### 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

# Contact information

#### Type(s)

Principal investigator

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**Public** 

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

#### Study type(s)

Diagnostic, Prevention, Screening, Efficacy

#### 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 Alenhanced 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** 

#### Phase

Phase I/II

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

Exo Iris (Exo Inc., Santa Clara, CA, USA)

#### Primary outcome(s)

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

#### Key secondary outcome(s))

- 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.

#### Completion date

# **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

#### Healthy volunteers allowed

No

#### Age group

Mixed

#### Lower age limit

0 days

# Upper age limit

24 weeks

#### Sex

All

#### 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 TOC 1N0

# Study participating centre Siksika Health Services

547 Highway 901

Siksika Canada TOJ 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

#### **ROR**

https://ror.org/0160cpw27

# Funder(s)

# Funder type

Charity

#### **Funder Name**

**Arthritis Society** 

#### Alternative Name(s)

Société de l'arthrite, Arthritis Society Canada | Toronto ON, Arthritis Society Canada

### 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., TD Bank (United States)

#### **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**

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes