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SHINE-2: Screening the hips in newborns. The use of an acoustic device to identify developmental hip dysplasia in babies

Submission date
20/08/2024

Recruitment status
No longer recruiting

Registration date
22/08/2024

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Developmental dysplasia of the hip (DDH) is a condition that affects the hip joint in babies. In severe cases, the hip can be dislocated, and in milder cases, the hip may not develop properly. DDH is a common cause of hip problems later in life, including osteoarthritis, and can lead to hip replacements, especially in people under 60. Early diagnosis is crucial for effective treatment, which may involve a simple splint if caught early in infancy.

In the UK, DDH is currently screened through a combination of physical examinations and selective ultrasound scans. However, physical exams are not always accurate, and as a result, about two out of three hip dislocations might be missed. An alternative method used in some European countries involves screening all babies with ultrasound, but this approach is expensive and often gives false positives.

The SHINE2 study aims to improve how we screen for DDH by developing a new tool that uses sound to detect hip problems in infants. The goal is to create a simple, safe, and cost-effective screening method that can be easily used by healthcare professionals with minimal training.

Who can participate?
Babies under 3 months old who are already scheduled for hip screening as part of the national screening program can participate in this study.

What does the study involve?
For babies participating in the study, the researchers will use the new sound-based screening tool in addition to the standard screening methods. This will help refine the tool and assess its effectiveness. The process is non-invasive and should not cause any discomfort to the babies.

What are the possible benefits and risks of participating?
There is no direct benefit to research participants however patients often welcome participating in a study that could benefit others with the same condition.
The safety of participants, parents and staff is of paramount importance. Prior to use, electrical

safety will be assured with an electronic Portable Appliance Test ('PAT-test'). The sounds used will be well within the recommended safety thresholds for new born babies, which advise 1) the hourly Leq should not exceed 50 dB; 2) the hourly L should not exceed 55 dB; 3) the 1 s Lmax should not exceed 70 dB. The vibration experienced will be akin to placing a headphone playing music against the infant's skin, with another headphone a specified distance away also against the skin listening for the sound transmitted. As far as possible, the device has been assembled from commercially available units, which have individually been certified by their manufacturers for sale. It comprises a USB-audio interface, an amplifier and associated wiring, running from a 240v mains supply. All the units are housed in a protective case rated to IP67, which provides an extra means of operator protection and prevents access to any of the internal units. The device is controlled by a standard Windows PC connected via USB. There are two attached parts which come into contact with the patient: the emitter and the detector. Both are housed in plastic enclosures which do not allow contact with internal components. The detector is purely passive. The emitter contains a commercial bone transducer which is powered by the amplifier. The amplifier can supply a maximum of 1.5A/12V. It generates a signal in the audible range 20-20000Hz. Sound level measurements have not been conducted but the audio volume is low in practice. We will carry out in-house electrical safety testing to EN 60601-1 1 "Medical electrical equipment — Part 1: General requirements for basic safety and essential performance".

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
August 2023 to August 2025

Who is funding the study?
The study is funded by the University of Liverpool and Alder Hey Children's NHS Foundation Trust (UK)

Who is the main contact?
Professor Daniel Perry, danperry@liverpool.ac.uk.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
324933

Central Portfolio Management System (CPMS)
56359

Protocol serial number
UoL001742

Study information

Scientific Title
SHINE-2: Screening the Hips in Newborns. The use of an acoustic device to identify developmental hip dysplasia in babies

Acronym
SHINE-2

Study objectives
Using developments in sensor technologies, we have experimented with acoustic sensors and sound transmission across joints. Through our previous project SHINE, we worked in the laboratory to develop the concept and refine the optimal means of sound transmission and detection though bone, along with optimal sound frequency (TRL1/2). We then developed a poof-of-concept device that could identify gaps within bone
continuity (TRL3). We then worked on this proof-of-concept in the laboratory and in the hospital environment; where we tested in on the hips of 150 babies. Through this, we were able to make refinements to the device, clarify the optimal means of device application and the optimal position of the baby. We were able to demonstrate signals of effectiveness.
However, the proof-of-concept has challenges to overcome, which include:
• Ensuring the device can be used by a single clinical user.
• Interpreting the signal to a meaningful output for the user

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/06/2023, Health and Social Care Research Ethics Committee A (HSC REC A) (Business Services Organisation, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 28 9536 1400; RECA@hscni.net), ref: 23/NI/0066

Primary study design
Other

Study design
Basic Science involving procedures with human participants

Study type(s)
Other

Health condition(s) or problem(s) studied
Developmental dysplasia of the hip (DDH)

Interventions
The assessment will involve an additional examination during routine ultrasound, which is being undertaken as part of the national selective screening program. In addition to the ultrasound examination, the child will have the prototype device applied (i.e. an external excitatory acoustic signal will be generated from an acoustic device that is placed on the knee. An external microphone will ‘listen’ and interpret the transmission of the acoustic signal across the hip, and any echoed back to the knee.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SHINE sensor - A novel device to enhance the detection of developmental dysplasia of the hip (DDH) in babies through specific audible tones and/or the transmission of vibration across the hip joint.

Primary outcome(s)
The sensitivity and specificity of the acoustic tool in the detection of DDH of the hip. The assessment will involve an additional examination during routine ultrasound, which being is undertaken as part of the national selective screening program. In addition to the ultrasound examination, the child will have the prototype device applied (i.e. an external excitatory acoustic signal will be generated from an acoustic device that is placed on the knee. An external microphone will ‘listen’ and interpret the transmission of the acoustic signal across the hip, and any echoed back to the knee).

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Male and females under 3 months old meeting the criteria for hip screening as part of the national screening program

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 Months

Upper age limit
3 Months

Sex
All

Key exclusion criteria
Children with joint contractures preventing normal body positioning during the routine neonatal examination (i.e. knee dislocation, arthrogryposis etc).

Date of first enrolment
05/10/2023

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Childrens NHS Foundation Trust
Eaton Road
Liverpool
United Kingdom
L14 5AB

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Alder Hey Children's NHS Foundation Trust

Alternative Name(s)
Alder Hey Children's Hospital NHS Foundation Trust, Alder Hey Children's Hospital

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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 as no suitable register exists.

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	version 2.0	14/06/2023	21/08/2024	No	Yes
Protocol file	version 1.0	13/03/2023	21/08/2024	No	No