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A study to find out whether gradually stopping brace treatment or stopping it all at once is better for babies with hip dysplasia

Submission date
30/04/2025

Recruitment status
Recruiting

Registration date
02/05/2025

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Developmental dysplasia of the hip (DDH) is a condition where a baby's hip joint does not develop properly, which can lead to dislocation. It affects about 1 in 100 babies. Treatment often involves wearing a soft brace called a Pavlik harness. However, doctors do not all agree on how the brace should be removed- some stop it all at once, while others gradually reduce brace use over time. This study aims to find out whether it is feasible to run a larger study comparing these two approaches.

Who can participate?
Babies under 6 months old who have been successfully treated in a Pavlik harness and have an ultrasound showing the hip has improved (alpha angle of at least 60 degrees). A parent or legal guardian must be able to provide consent and complete study questionnaires.

What does the study involve?
Families who agree to take part will be randomly allocated to one of two existing care strategies: immediate removal of the brace, or continued night-time wear for four weeks (weaning). Parents will complete short questionnaires about how their baby and family are doing at the start of the study and again at 2, 4 and 6 weeks. These can be completed online or over the phone. The study will also use routine hospital data to look at outcomes like follow-up appointments, hip scans, and any need for further treatment.

What are the possible benefits and risks of participating?
There is no guarantee of benefit, but the study may help improve how future babies are treated for DDH. The risks are low because both care options are already used in NHS hospitals. Some babies may experience minor skin irritation or discomfort from the brace, but these risks are part of standard care. Participation also involves some time from parents to complete questionnaires.

Where is the study run from?
The study is led by the University of Liverpool and will be carried out in NHS hospitals in the UK.

When is the study starting and how long is it expected to run for?
September 2024 to September 2026. The study recruitment is expected to start in September 2025 and run for twelve months.

Who is funding the study?
The National Institute for Health and Care Research (NIHR)

Who is the main contact?
Dr Joanna Craven, University of Liverpool, joanna.craven@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
68841

Integrated Research Application System (IRAS)
354869

National Institute for Health and Care Research (NIHR)
303304

Protocol serial number
UoL001920

Study information

Scientific Title
The WINDY study- Weaning in INfant hip Dysplasia- a randomised multicentre feasibility study of weaning of brace treatment versus immediate cessation for developmental dysplasia of the hip

Acronym
WINDY

Study objectives
The study aims to assess whether it is feasible to run a larger randomised trial comparing two common ways of stopping brace treatment in babies with developmental dysplasia of the hip. The two approaches are either stopping the brace all at once or gradually reducing the time the brace is worn by using it at night only for four weeks. The study will also explore how acceptable the study design is to families and clinicians and whether parent-reported outcome measures and routinely collected clinical data can be used effectively in future research.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/06/2025, North West – Haydock (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048138, (0)207 104 8131, (0)2071048117; haydock.rec@hra.nhs.uk), ref: 25/NW/0173

Study design
Multicentre parallel two-group feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
The strategy for discontinuing Pavlik harness treatment in infants under 6 months with Developmental Dysplasia of the Hip (DDH) following successful Pavlik harness use.

Interventions
This is a multicentre, open-label, randomised controlled feasibility trial comparing two approaches to ending Pavlik harness treatment in infants with developmental dysplasia of the hip (DDH). Following informed consent, participants are randomly allocated in a 1:1 ratio to one of two arms using a secure web-based system (REDCap), stratified by site. The intervention arm involves weaning, defined as wearing the Pavlik harness at night only (minimum 10 hours per night) for four weeks following the completion of full-time use. The control arm involves immediate cessation of the Pavlik harness with no further brace use.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pavlik harness

Primary outcome(s)

Acceptability of trial design measured using the monthly recruitment rate per centre and the percentage of eligible infants randomised at the end of the 6-month recruitment period.

Key secondary outcome(s))
1. Parental engagement measured using self-reported compliance questionnaires and EMBRACE completion rates at baseline, 2, 4, and 6 weeks post-randomisation
2. Reliability of the EMBRACE measured using floor and ceiling effects, test-retest reliability (Intraclass Correlation Coefficient), and Cronbach's alpha at 2 and 4 weeks post-randomisation
3. Validity of the EMBRACE measured using correlation with visual analogue scale (VAS) scores at baseline, 2, 4, and 6 weeks post-randomisation
4. Acceptability of the EMBRACE measured using the average time taken to complete the questionnaire and percentage of missing data at baseline, 2, 4, and 6 weeks post-randomisation
5. Accessibility of Smart4NIPE data measured using the availability of routinely collected clinical data at baseline
6. Accuracy and completeness of Smart4NIPE data measured using a comparison of the data points recorded in Smart4NIPE with those entered into REDCap at baseline
7. Acetabular dysplasia measured using the most recent routine ultrasound or radiograph (BSCOS core measurement set or acetabular index) at 12 weeks post-randomisation
8. Reintervention rate measured using the clinician-reported requirement for further bracing or surgery at 12 weeks post-randomisation
9. Impact on the family unit measured using EMBRACE questionnaire scores at baseline, 2, 4, and 6 weeks post-randomisation
10. Hospital attendances related to DDH measured using the recording of the number of appointments from randomisation to 12 weeks
11. Adverse events measured using data recording any clinician-reported foreseeable or serious adverse events throughout the 12-week follow-up period

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. The infant has commenced Pavlik harness treatment under 6 months of age
2. The infant has completed a period of full-time Pavlik harness wear
3. Alpha angle is at least 60 degrees at the time of randomisation
4. The parent or legal guardian is willing and able to provide informed consent for participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 days

Upper age limit

6 months

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The infant has, or is suspected to have, a neuromuscular condition
2. The parent or legal guardian is unable to adhere to the study procedures or complete the questionnaires
3. The parent or legal guardian is unable to provide informed consent

Date of first enrolment
01/11/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Alderhey Childrens Hospital
Eaton Road
Liverpool
England
L122AP

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre

University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

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

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: the University of Liverpool Research Data Catalogue. A DOI-linked dataset will be deposited following publication of the main results.

The dataset will include fully de-identified participant-level data used for analysis, including trial outcome measures, feasibility metrics, and participant-reported outcomes from the EMBRACE questionnaire. Personally identifiable information (such as names and contact details) will not be shared.

Data availability:
Data will be made available after publication of the main study findings and will be stored in perpetuity.

Access criteria and mechanism:
Data will be openly accessible via the University of Liverpool Research Data Catalogue under a DOI, with appropriate metadata, a data dictionary, and documentation to ensure usability. No request is required for access, but users will be advised to cite the dataset accordingly.

Consent and anonymisation:
Informed consent for data sharing and storage of de-identified data was obtained from parents or legal guardians. All shared data will be fully anonymised to remove any possibility of participant identification.

Ethical and legal compliance:
Data handling complies with the UK GDPR, Data Protection Act 2018, and institutional data protection policies. Access to identifiable data remains restricted to authorised research team members only.

Other comments:
No biological samples are involved. The data shared will support replication and secondary analyses by other researchers working on developmental dysplasia of the hip or related areas in paediatric orthopaedics.

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes