

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

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Registration date 02/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/07/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number
354869

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR303304, CPMS 68841

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

Old ethics approval format

Ethics approval(s)

Pending submission

Study design

Multicentre parallel two-group feasibility randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Hospital

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Pavlik harness

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/09/2024

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

Age group

Child

Lower age limit

1 Days

Upper age limit

6 Months

Sex

Both

Target number of participants

60

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

01/09/2025

Date of final enrolment

01/03/2026

Locations**Countries of recruitment**

England

United Kingdom

Wales

Study participating centre

Alderhey Childrens Hospital

Eaton Road

Liverpool

United Kingdom

L122AP

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

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
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Study participating centre
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Sponsor type
University/education

Website

<https://www.liverpool.ac.uk/>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/09/2027

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

Stored in publicly available repository, Available on request