

# Ultrasound imaging in the management of clinical neonatal hip instability - a randomised controlled trial

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/01/2009	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

### Acronym

The Hip Trial

### Study objectives

To assess the clinical effectiveness and cost effectiveness of a policy of ultrasound imaging to guide the decision about whether to initiate treatment for clinical hip instability in neonates. In particular the trial will assess whether the reduction in the use of splinting following ultrasound diagnosis is associated with an increased need for late treatment

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Diagnostic

### Participant information sheet

### Health condition(s) or problem(s) studied

Neonatal hip instability

### Interventions

Ultrasound imaging to guide the decision about whether to initiate treatment for clinical hip instability in neonates/control.

### Intervention Type

Other

### Phase

Not Applicable

**Primary outcome measure**

X-ray appearance between 12 and 24 months used as a measure of hip function, proportion of babies splinted; proportion of babies needing surgery; financial burden on families and the health services; psychosocial impact on families

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/12/1994

**Completion date**

01/01/2001

## Eligibility

**Key inclusion criteria**

Babies less than 6 weeks old with a clinical suspicion of neonatal hip instability

1. Suspicion confirmed by a second doctor
2. There is clinical uncertainty about whether the decision to initiate treatment should be guided by ultrasound examination

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

629

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/12/1994

**Date of final enrolment**

01/01/2001

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Medical Statistics Unit**  
London  
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## Sponsor information

**Organisation**  
Medical Research Council (UK)

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**Sponsor type**  
Research council

**Website**  
<http://www.mrc.ac.uk>

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Medical Research Council (UK) (ref: G9312055)

**Alternative Name(s)**  
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2002		Yes	No
<a href="#">Results article</a>	results	01/01/2005		Yes	No