

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

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

Protocol serial number
G9312055

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

Study participating centre

Medical Statistics Unit

London

United Kingdom

WC1E 7HT

Sponsor information

Organisation

Medical Research Council (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	results	01/12/2002		Yes	No
Results article	results	01/01/2005		Yes	No