A prospective randomised controlled clinical trial to evaluate methods of dressing removal, in respect of time and comfort, for boys undergoing hypospadias repair

Submission date	Recruitment status No longer recruiting	Prospectively registered	
12/09/2003		☐ Protocol	
Registration date 12/09/2003	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 17/12/2008	Condition category Urological and Genital Diseases	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N0206121779

Study information

Scientific Title

Study objectives

Does a new dressing technique used around the penile wound post hypospadias repair reduce the time taken to remove the dressing and reduce the pain experienced by children and parental anxiety?

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Hypospadias repair

Interventions

New dressing technique vs standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Removal time for dressing

Key secondary outcome(s))

- 1. Self reported parent/carer anxiety pre and post dressing removal
- 2. Differences in child pain score (0-4 visual analogue scale) rated by parent and nurse

Completion date

01/09/2004

Eligibility

Key inclusion criteria

All boys undergoing any type of hypospadias repair that would require a form of dressing post operatively, between the ages of 15 months, up to 5 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

15 months

Upper age limit

5 years

Sex

Male

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2003

Date of final enrolment

01/09/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Ward K3

Liverpool United Kingdom L12 2AP

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Royal Liverpool Children's NHS Trust (UK)

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	01/08/2003		Yes	No