

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/12/2008	<b>Condition category</b> Urological and Genital 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

### Contact name

Ms C Sanders

### Contact details

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Eaton Road  
Liverpool  
United Kingdom  
L12 2AP

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Not Specified

## Participant information sheet

### 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 measure

Removal time for dressing

## **Secondary outcome measures**

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

## **Overall study start date**

01/09/2003

## **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

## **Age group**

Child

## **Lower age limit**

15 Months

## **Upper age limit**

5 Years

## **Sex**

Male

## **Target number of participants**

A sample size of 30 children in each group will be recruited. Control group or treatment group.  
Total = 60.

## **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**

England

United Kingdom

**Study participating centre**

**Ward K3**

Liverpool

United Kingdom

L12 2AP

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Royal Liverpool Children's NHS Trust (UK)

## **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	01/08/2003		Yes	No