

# Randomisation to topical corticosteroids or placebo for the treatment of the non-retractile foreskin

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/11/2015	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0453141246

# Study information

## Scientific Title

Randomisation to topical corticosteroids or placebo for the treatment of the non-retractile foreskin

## Study objectives

To assess whether it is the corticosteroid alone or the gentle physical retraction combined with ointment that is responsible for the results previously observed with topical corticosteroid treatment of the non-retractile foreskin. Two steroid preparations are currently used within Manchester so the study will be carried out using both preparations to see if there is a significant difference between them.

## 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)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Urological and Genital Diseases: Penile diseases

## Interventions

Boys of 3 years and above who are referred to the outpatient clinic with a physiological non-retractile foreskin will be invited to participate in the study. The boys and their parent/carer will be interviewed by the primary investigator and given the patient information sheet. If they agree to participate in the study, written consent will be obtained. The patient will be randomised by the pharmacy department to receive either placebo, 1% hydrocortisone or 0.1% betnovate ointment. The parents will be instructed to apply the ointment to the tip foreskin every morning and evening for 6 weeks.

The patients will be assessed by the primary investigator after 6 weeks. If the treatment has

been successful, ie. the foreskin is retractile, no further treatment is given. If the treatment has been unsuccessful, ie. partial or no retraction, the patients will be offered corticosteroid ointment (0.1% betnovate as this is the more potent steroid) for a further 6 weeks, following which time they will be reassessed. After 6 months all patients will be reassessed and foreskin retractility will be graded (full/partial/no retraction). The code for which ointment each patient used will be broken at the end of the study. All patients with persistent problems such as infection or a non-retractile foreskin at the end of the study period will be offered circumcision. All results will be recorded on data sheets in the patient's records and on a confidential database.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Retraction of the foreskin

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2002

**Completion date**

01/01/2005

**Eligibility****Key inclusion criteria**

Boys of 3 years and over with a physiological non-retractile foreskin

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

3 Years

**Sex**

Male

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/10/2002

**Date of final enrolment**

01/01/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Central Manchester & Manchester Children's University Hospitals BH

Manchester

United Kingdom

M9 7AA

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Central Manchester and Manchester Children's University Hospitals NHS Trust (UK)

**Funder Name**

Unfunded

**Funder Name**

NHS R&D Support Funding

## **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