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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2015	Urological and Genital Diseases	[_] Record updated in last year

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
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

Study type(s)
Treatment

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(s)
Retraction of the foreskin

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Sex
Male

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
United Kingdom

England

Study participating centre
Central Manchester & Manchester Children's University Hospitals BH
Manchester
United Kingdom
M9 7AA

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration