Long term follow up in boys operated for hypospadias.

A study into functional and cosmetic results.

Published: 23-10-2007 Last updated: 10-05-2024

To study long term results of hypospadias surgery in childhood

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Penile and scrotal disorders (excl infections and inflammations)

Study type Observational non invasive

Summary

ID

NL-OMON31413

Source

ToetsingOnline

Brief title

Hypospadias, long term follow-up

Condition

Penile and scrotal disorders (excl infections and inflammations)

Synonym

congenital abnormality of the penis, hypospadias

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cosmetical, Hypospadias, Long term follow-up, urodynamic

Outcome measures

Primary outcome

IPSS (International Prostate Symptom Score), IIEF (International Index of

Erectile Function), NRV (Nederlandse Relatie Vragenlijst), cosmetical aspect,

penile length, Qmax and post void residual.

Secondary outcome

None

Study description

Background summary

On the long term cosmetical and/or functional problems with voiding or erections are encountered after hypospadias surgery performed at young age. Also, psychologic burden can be high in patients operated after the age of 2 years, incase of complications or suboptimal results.

Study objective

To study long term results of hypospadias surgery in childhood

Study design

This is an observational cohort study.

Study burden and risks

The study consists of three questionnaires and one visit to the outpatient clinic for physical examination and uroflowmetry (non invasive)

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Willing and able to participate in the study, signed informed consent.

Exclusion criteria

NA

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-10-2007

Enrollment: 119

Type: Actual

Ethics review

Approved WMO

Date: 23-10-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

CCMO NL18265.041.07