A comparison of long-term results of the single stage Fowler-Stephens orchidopexy versus the two-stage Fowler-Stephens orchidopexy.

Published: 29-10-2013
Last updated: 22-04-2024

Primary: To study the long-term testicular position, volume and vascularisation of patients who have undergone the single stage Fowler-Stephens orchidopexy and the 2-stage Fowler-Stephens orchidopexy.Secondary: 1) To determine which of the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Male genital tract therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON38694

Source
ToetsingOnline

Brief title
FSO-1 vs. FSO-2

Condition

- Male genital tract therapeutic procedures

Synonym
Cryptorchidism, undescended testis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KCHOMP

Intervention

Keyword: follow-up, Fowler-Stephens orchidopexy, long-term results, quality of life

Outcome measures

Primary outcome

Main endpoint: volume of the FSO-testis

Secondary outcome

Secondary endpoints: testicular position and testicular vascularisation.

Study description

Background summary

The Fowler-Stephens orchidopexy is a surgical technique for high intra-abdominal testes in which the testicular artery and vein are ligated to create sufficient length for tension free placement of the testis in the scrotum. To increase collateral circulation prior to mobilization of the testis, a 2-stage Fowler-Stephens orchidopexy was devised in which mobilization of the testis and fixation in the scrotum occurs in a second tempo. Although both techniques are widely applied, superiority of either technique has not been proven. Success rates published to date are mainly retrospective analyses of medical records and lack long-term follow-up of treated patients. Long-term results are needed as patients included in these studies were relatively young and had not yet undergone final growth of the testes. Long-term growth potential of the treated testes is functionally and cosmetically important for patients. It is possible the success of the procedures may only be determined during puberty or in the postpubertal period.
We hypothesize that both procedures are equally effective. Therefore the single stage Fowler-Stephens orchidopexy is the preferred technique as it spares patients a second operation.

Study objective

Primary: To study the long-term testicular position, volume and vascularisation of patients who have undergone the single stage Fowler-Stephens orchidopexy and the 2-stage Fowler-Stephens orchidopexy.
Secondary: 1) To determine which of the procedures, the single stage

Fowler-Stephens orchidopexy or the 2-stage Fowler-Stephens orchidopexy, is superior in terms of testicular functionality and cosmetics.
2) To determine if and when growth of the operated testicle stagnates in the postoperative period.
3) To determine if quality of life is affected by the outcome of the operation.

Study design

A multi-center long-term follow-up study.

Study burden and risks

We did not identify any risks for participating patients. Patients will have to travel to a nearby Academic hospital as to undergo clinical examination and a color Doppler ultrasound of both testes. Travel expenses will be refunded.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria: Primarily the subject must have undergone either the single stage Fowler-Stephens orchidopexy or 2-stage Fowler-Stephens orchidopexy after January 1st 1995 and be aged between 12 * 17 years at time of inclusion.

Exclusion criteria

We will exclude subjects if any of the following is present in their medical history: prune-belly syndrome, epididymitis, chromosomal or hormonal abnormalities, hormonal medication or presence of a testicular germ cell tumor.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-10-2013
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL45599.018.13