Testicular volume after inguinal hernia repair at childhood. Explorative study.

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to study testicular volumes after inguinal herniotomy at childhood.

Ethical review	Approved WMO
Status	Pending
Health condition type	Testicular and epididymal disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35383

Source
ToetsingOnline

Brief title
TeVoLiK

Condition

- Testicular and epididymal disorders

Synonym
groin rupture, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: subsidie aangevraagd bij Pieter van Foreest instituut

Intervention

Keyword: inguinal hernia repair, testicular volume

Outcome measures

Primary outcome

testicular volume, measured by ultrasound

Secondary outcome

testicular position and volume measured by Prader orchidometer

Study description

Background summary

Testicular atrophy is a complication after inguinal herniotomy in children. Percentage described in the literature varies from 1 to 38% [1-4].
It is imaginable inguinal operation at childhood has his long-term effects. The funniculus, with spermatic fascia, cremaster muscle, ductus deferens, spermatic artery and vein, can be damaged. This can cause a reduce in growth -and function [5]- of the testicle.
The Leung et al. [6] studied the precize volumina of the testicles after herniotomy at childhood [6]. They documented in 0.58 and 10% of the boys a respectively more than 50 en 25% decrease in testicular volume on the operated side when compared with the non-operated side.
An important limitation of this study is -as described in their discussion- 'the testicular volumes of the operated and normal sides of the same patient were compared since we believe it is very difficult, if not impossible, to obtain a 'normal range' of testicular volume in a specific age group.
Because our research group recently created this 'normal ranges', we hope to improve the study of testicular volume after inguinal herniotomy at childhood.

1. Friedman, D., Schwartzbard, A., Velcek, F. T. et al.: The government and the inguinal hernia. J Pediatr Surg, 14: 356, 1979
2. McGregor, D. B., Halverson, K., and McVay, C. B.: The unilateral pediatric inguinal hernia: Should the contralateral side by explored? J Pediatr Surg, 15: 313, 1980
3. Puri, P., Guiney, E. J., and O'Donnell, B.: Inguinal hernia in infants: the fate of the testis following incarceration. J Pediatr Surg, 19: 44, 1984
4. Surana, R. and Puri, P.: Is contralateral exploration necessary in infants with unilateral inguinal hernia? J Pediatr Surg, 28: 1026, 1993
5. Takihara, H., Cosentino, M. J., Sakatoku, J. et al.: Significance of testicular size measurement in andrology: II. Correlation of testicular size with testicular function. J Urol, 137: 416, 1987

6. Leung, W. Y., Poon, M., Fan, T. W. et al.: Testicular volume of boys after inguinal herniotomy: combined clinical and radiological follow-up. Pediatr Surg Int, 15: 40, 1999

Study objective

to study testicular volumes after inguinal herniotomy at childhood.

Study design

study population
inclusion:
- boys who underwent inguinal herniotomy between 1999-2008 - acute or elective- before the age of 16 years in the Medical Centre Alkmaar.
- age at follow-up 9-13 years.

exclusion:
- abnormalities at scrotum / testis (eg torsio testis)
- chromosomal abnormalities

Ca. 200 boys will reach the inclusion criteria. With a response of 50% we will include ca. 100 boys.

clinical examination
* position of the testes
* testicular volume
- prader orchidometer
- ultrasound

data will be analysed by SPSS

Study burden and risks

One visit to the outpatient clinic for a pain-free clinical examination without any risk.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminastraat 12
1815 JD Alkmaar
NL

Scientific
Medisch Centrum Alkmaar

Wilhelminastraat 12
1815 JD Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- male
- inguinal hernitomy between 1999 - 2008 before the age of 16 years in the medical Centre Alkmaar
- age of 9-13 years at the time of follow-up.

Exclusion criteria

- abnormalities of scrotum of testis (eg. torsio testis)
- chromosomal abnormalities

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-04-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL29613.094.09