Prevalence of testicular microlithiasis in patients with Down syndrome

Published: 05-08-2008
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Determining the prevalence of testicular microlithiasis in Down syndrome.

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

Summary

ID

NL-OMON31771

Source
ToetsingOnline

Brief title
Testicular microlithiasis in patients with Down syndrome

Condition

- Testicular and epididymal disorders

Synonym
calcifications, testicular microlithiasis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Ministerie van OC&W,financiering vindt plaats uit eigen middelen (research rekening Kindergeneeskunde MCA)

Intervention

Keyword: Down syndrome, prevalence, testicular cancer, Testicular microlithiasis

Outcome measures

Primary outcome

The prevalence of testicular microlithiasis in Down syndrome.

Secondary outcome

Volume and position of both testes.

Study description

Background summary

Testiculair microlithiasis is an entity characterized by calcifications in the seminiferous tubule of the testis (-es). It is readily diagnosed by the ultrasonographic appearance of small hyperechoic foci typically scattered throuhout the testis. Apparently asymptomatic in itself and often an incidental finding. Testicular microlithiasis is associated with benign states as well as pathological conditions. Clinical concern is primarily focused on the high association of testicular cancer with testicular microlithiasis. Since the incidence of testicular tumors appears to be increased in Down syndrome, testicular microlithiasis in Down syndrome has particular interest.

Study objective

Determining the prevalence of testicular microlithiasis in Down syndrome.

Study design

The prevalence of testicular microlithiasis and the volume of both testes (from patients with Down syndrome whose ages ranges from 0-25 years) will be determined using ultrasonography. The results will be noted on a apart form and the data will be recorded in a statistical program.

Study burden and risks

The risks associated with participation are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Boys/ men with down syndrome confirmed by chromosomal evaluation.
Age: 0 - 18 years.

Exclusion criteria

Disorders of the testes/ scrotum (torsio testis, hydrocele)
Operations of the testis (-es) in thepast, like torsio testis, undescended testis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2008
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	NL21126.094.07