

Establishing of normative values for testicular volume measured by ultrasonography in boys from 0-18 years old.

Published: 20-12-2006

Last updated: 14-05-2024

The purpose of the study is to establish normative values of the size of the testis measured by ultrasonography in childhood, through puberty till adulthood. (0-18 years)

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

Summary

ID

NL-OMON30352

Source

ToetsingOnline

Brief title

normative values for testicular volume measured by ultrasonography

Condition

- Testicular and epididymal disorders

Synonym

testicular volume, undescended testis

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

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

Intervention

Keyword: child, testicular size, ultrasonography

Outcome measures

Primary outcome

Normative values for testicular volume measured by ultrasonography in boys from 0 to 18 years old.

Secondary outcome

n.v.t.

Study description

Background summary

Until now, measurement of testicular volume was mainly performed by using a Prader orchidometer. Recent studies showed that testicular volume measured by ultrasonography is considered to be the best method. However, there are no normative values of the size of the testis measured by ultrasonography in childhood, through puberty till adulthood.

Study objective

The purpose of the study is to establish normative values of the size of the testis measured by ultrasonography in childhood, through puberty till adulthood. (0-18 years)

Study design

The testicular volume of both testes (from boys whose ages ranges from 0-18 years) will be determined using a Prader orchidometer and by ultrasonography. The results will be noted on an apart form and the normative values for each age-group (from 0-18 years) will be established.

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)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Both testes have to be descended in a low scrotal position (from birth)
- Age : 0-18 years

Exclusion criteria

- A non-scrotal testis (congenital or acquired)
- Other disorders of the testes/ scrotum (torsio testis, hydrocele)
- Operations in the inguinal region (in the past), like for example orchidopexy, hernial

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corrections etc.

- Operations of the testis(-es) (in the past), like torsio testis
- A undescended testis in the past
- A chromosomal defect

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2007

Enrollment: 600

Type: Anticipated

Ethics review

Approved WMO

Date: 20-12-2006

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

CCMO

ID

NL14665.094.06