# The inguinal testis; how accurate is the volume measurement

Published: 12-03-2012 Last updated: 30-04-2024

The purpose of this study is to evaluate the accuracy of the measurement of testisvolume located in the groin area. We hypothesize that the inguinal testis has a smaller volume compared to the normal value for the same age at a scrotal position....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Testicular and epididymal disorders
Study type	Observational invasive

# Summary

#### ID

NL-OMON37604

**Source** ToetsingOnline

**Brief title** Volume of the testis located in the groin area

## Condition

• Testicular and epididymal disorders

Synonym undescended testis

**Research involving** Human

## **Sponsors and support**

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

## Intervention

Keyword: orchidopexie, ultrasound, undescended testis, volume

#### **Outcome measures**

#### **Primary outcome**

The primary outcome parameter is the testicular volume, pre- operatively,

during orchidopexy and post-operatively.

#### Secondary outcome

not applicable

# **Study description**

#### **Background summary**

A recent study by the Alkmaar research group showed that in three out of four boys with acquired undescended testis, the testis spontaneous descents at the beginning of puberty.

Testisvolume is an important markter for the development of the testis and for the different puberty stages.

For inguinal testis the follow-up of the testisvolume is complicated by its location.

It is unclear whether the volume measured while the testis is located in the groin region is a valid measure.

To our knowledge it has not been investigated how the measured volume of the inguinal testis compared with the same testis in scrotal position is correlated.

#### **Study objective**

The purpose of this study is to evaluate the accuracy of the measurement of testisvolume located in the groin area.

We hypothesize that the inguinal testis has a smaller volume compared to the normal value for the same age at a scrotal position.

However, it is unclear whether the inguinal testisvolume is substantially behind or that the volumes measured are affected by the testis location during measurement.

#### Study design

All boys, aged 2-12 years, who will undergo an orchidopexy at our hospital will be asked to participate in this study.

Just before the start of the operation a volumemeasurement will be made \*\*by means of ultrasonography and orchidometer of the undescended testis located in the groin area.During the orchidopexy a volume measurement using the slide caliper will be performed.

We will determine the length, breadth and depth of the testis with ultrasound and with the slide caliper. The testicular volume will be calculated using the formula; D1 (length) x D2 (width) x D3 (depth) x pi / 6.

The participating boys will be seen two-times postoperative at the outpatient clinic, after 6 weaks and 6 months respectively. This is in line with the current protocol for boys who undergo orchidopexy. For those boys that participate in this study an additional volume measurement will be performed. The volume measurement with orchidometer and ultrasound will be repeated using the same method. Considering that the testis will have a scrotal position at that time.

The primary outcome parameter is the testicular volume, pre- operatively, during orchidopexy and post-operatively.

Statistical analysis will take place using SPSS, anonymous. The agreement between the measurement methods will be tested using the Bland-Altman plot and intraclass correlation coefficient (ICC).

The volume will be correlated with the normal values \*\*for testicular volume as recently defined by the study group of Alkmaar. (Goede et al)

#### Study burden and risks

The burden and risk associated with participation are negligible There are no additional follow up moments. The subject receives only two additional ultrasounds during regular follow-up at the outdoor patient clinic. This is a non- invasive procedure without risks. During the orchidopexy a slide caliber will be used to measure the volume, this is indeed an invasive procedure. The risks of this invasive procedure are negligible, in particular when it is used by an experienced surgeon or urologist.

# Contacts

**Public** HagaZiekenhuis sportlaan 600 2566MJ Den Haag NL **Scientific** HagaZiekenhuis

sportlaan 600 2566MJ Den Haag NL

# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Children (2-11 years)

## **Inclusion criteria**

-male -between 2 and 12 years of age. -diagnosed with undescended testis for wich an orchidopexy is indicated

## **Exclusion criteria**

medical history of;

- epidydimitis,torsio testis
- -chromosal or hormonal abnormalities, use of hormonal medication,
- -orchidopexy ipsi lateral or other inguinal surgery

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

#### Recruitment

МП

INL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	50
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	12-03-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

# **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

ССМО

**ID** NL38512.098.11