# Long-term testicular position, volume and 18F-FDG-uptake after orchidopexy of congenital undescended testis.

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Evaluation of long-term position, volume and FDG-uptake of the orchidopexied testis because of congenital undescended testis.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Endocrine gland therapeutic procedures |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON39805

**Source**
ToetsingOnline

**Brief title**
Testis after ORP on PET.

### Condition

- Endocrine gland therapeutic procedures

**Synonym**
cryptorchidsm, undescended testicle

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Alkmaar
**Source(s) of monetary or material Support:** geen

## Intervention

**Keyword:** congenital undescended testis, orchidopexy, PET/CT, volume

## Outcome measures

### Primary outcome

- FDG-uptake testes (PET-CT-scan)

- SUV max/mean

- laterality-index left/right testes

### Secondary outcome

- testis position

- testis volume as measured by ultrasound

- testis volume as measured by PET-CT-scan

- correlations above mentioned

# Study description

### Background summary

Long-term consequences of orchidopexy for congenital undescended testis on fertility are hardly known. Partly, this is because evaluation of the seperate function of both testes is difficult.
The PET-CT-scan, which shows the FDG-uptake (parameter for metabolism) of both testicles apart from each other, seems a promosing research on the funtion of the testis after orchidopexy.
We hypothesise the orchidopexied testis has a lower metabolism than the contralateral testis and lower than the testis in men of the general population.

### Study objective

Evaluation of long-term position, volume and FDG-uptake of the orchidopexied testis because of congenital undescended testis.

### Study design

long-term follow-up study

### Study burden and risks

Men will be requested to participate in the study and visit the MCA once to receive

- a short questionnaire
- physical examination
- ultrasonographic examination
- PET-CT-scan

The short questionnaire, physical and ultrasonographic examination are painless, without any risks and will take a quarter of an hour.

Adverse effects of the PET-CT are not expected. The PET-CT has a certain radiation burden since every radiation is potentially harmful. However, concerning radioactive exposure, the study protocol is designed according to the ALARA principle (As Low As Reasonably Achievable). For a 75 kg man the radiation burden will approximately be 2 mSv (whereas for a regular PET-CT, the radiation burden is between 6-10 mSv).

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- orchidopexy because of congenital undescended testis between 1984 and 1994 in the Medical
Centre of Alkmaar
- signed informed consent form.

## Exclusion criteria

- other testicular abnormality, currently or in past
- not yet reached puberty stage 5 according to Tanner
- diabetes
- incontinence
- kidney failure
- participation in a medical experiment in which radioisotopes were administered in the previous 12 months

# Study design

## Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2013 |
| Enrollment: | 15 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 22-03-2013 |
| 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 | NL42125.094.12 |