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.

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

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