# Early detection of carcinoma in situ of the testis with a new non-invasive method.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Reproductive and genitourinary neoplasms gender unspecified NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39915

**Source**
ToetsingOnline

**Brief title**
ScreenCIS

### Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Testicular and epididymal disorders

**Synonym**
Carcinoma in situ, pre-stage testicular cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W,SUWO en mogelijk Het

Zeldzame Ziekte Fonds en World Cancer Research Found.

## Intervention

**Keyword:** carcinoma in situ (CIS), non-invasive screening, OCT3/4, testicular germcell tumour (TGCT)

## Outcome measures

### Primary outcome

- Reproductive hormones; FSH, LH, testosterone and Inhibin-B

- DNA-isolation from blood: identification of TGCT risico SNPs

- Semen analysis; volume, concentration, number, motility and pH

- Semen diagnostic on the presence of OCT3/4 immunohistochemistry

- Semen diagnostic on the presence of TGCT miRNA

- Andrological history / Andrological history through web-based questionnaire

- Physical examination of the scrotum

- Scrotal ultrasound

- Testis biopsy

### Secondary outcome

Not applicable

# Study description

### Background summary

Almost all testiculaire germ cell tumours (TGCT) have carcinoma in situ (CIS) as common precursor. Epidemiologic data shown that 70% of the men with CIS of the testis develop within 7 years a clinically manifest tumour. Early detection of CIS is of large clinical value, because CIS can be threated with a low dose of local radiotherapy. Moreover radical orchidectomy, chemotherapy and/or radiotherapy are prevented, the treatment at a more advanced tumour stage, as

well as the long term complications of these invasive therapy.

## Study objective

The aim of this research is developing a non-invasive a method of early detection of CIS using scrotal ultrasound and semen diagnostic on CIS-cells. The results of this research will be used for the set-up of a screening study of CIS at men with an increased risk of testicular cancer.

Primary question: Is a non-invasive method of early detection of CIS clinically applicable in a future screening project of early detection of CIS of the testis at men with an increased risk of testicular cancer?

Secondary questions:
- What are the sensitivity, specificity and positive predictive value of scrotal ultrasound for early detection of testicular cancer with respect to the testis biopsy (gold standard)?
- What are the sensitivity, specificity and positive predictive value of semen diagnostic on CIS-cells for early detection of testicular cancer with respect to the testis biopsy (gold standard)?
- What are the sensitivity, specificity and positive predictive value of semen diagnostic on TGCT miRNA for early detection of testicular cancer with respect to the testis biopsy (gold standard)?
- What are the sensitivity, specificity and positive predictive value of bloodsamples on TGCT risico SNP's diagnostic for early detection of testicular cancer with respect to the testis biopsy (gold standard)?
- What is the difference in the increased risk of a testicular tumor, and thus the presence of CIS and/or positive outcomes of the non-invasive method for early detection of testicular cancer, among oligoasthenospermic men, men with cryptorchidism, and men with azoospermia?

## Study design

Pilot study, prospective, controlled clinically diagnostic research.

## Study burden and risks

The two patient groups receive the usual treatment, they underwent no extra researches within the framework of the study. The patient groups experiences therefore no extra risks or tax for participating to the research, however, having them possibly the advantage of early detection of CIS.

The two control groups undergoes within the framework of the research, beside their usual treatment, extra a blood purchase (6+7 ml), twice semendiagnostics and a scrotal ultrasound. There are no risks linked for men from the control groups to the additional researches which take place within the framework of

the study and these researches are just a little incriminating for the patient. The chance on finding CIS in this group is small, but at presence of CIS in the testis they have the advantage of early detection.

For men who in an earlier version of the current protocol (up to version 2.0, August 26, 2009) are included and men who participated in the Crypto-study (up to and including Amendment 2 of December 16, 2009) and/or the VASA study two additional semen analyses and semen diagnostics will be performed and a blood sample will be taken (6 mL). They get the results of the semen analyses subsequent to participation in the study and may have the benefit of early detection of CIS.

Men who are enrolled through Amendment 3 (August 30, 2012) of the Crypto-study get an extra semen analysis. They get the results of the semen analysis subsequent to participation in the study and may have the benefit of early detection of CIS.

## 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

Men of 18 years and older with:
- Patientgroup 1: riskfactors for TGCT
- Patientgroup 2: riskfactors for TGCT and testicular microcalcifications
- Controlegroep 1: normospermia and no riskfactors for TGCT
- Controlegroep 2: proven fertility

### Exclusion criteria

- Men < 18 years
- Retrograde ejaculation
- Sterlised
- Previous chemotherapy

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-01-2010 |
| Enrollment: | 403 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 12-10-2009 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 27-05-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-12-2014 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 18-02-2015 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 | NL28357.078.09 |