

Semen characteristics and testosterone levels in the general population

Published: 09-01-2019

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1. Evaluation of the variation of semen characteristics in the general population
2. Evaluation of the variance of testosterone levels in the general population

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON55724

Source

ToetsingOnline

Brief title

Semen characteristics and testosterone levels in the general population

Condition

- Endocrine disorders of gonadal function
- Sexual function and fertility disorders

Synonym

fertility, sperm quality

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: KWF

Intervention

Keyword: reference values, reproduction, semen analysis, testosterone

Outcome measures

Primary outcome

Semen characteristics, including volume, sperm concentration and fraction of progressive motile spermatozoa) and testosterone levels.

Secondary outcome

Not applicable.

Study description

Background summary

Age-specific reference values for semen characteristics and testosterone levels in the general population are lacking, but can positively strengthen research concerning impaired spermatogenesis en testosterone deficiency in high risk populations. A general population control group is essential for the DCOG-LATER male gonadotoxicity study, which will provide an accurate estimate of overall and treatment specific relative and absolute risks of azoospermia and testosterone deficiency in male survivors of childhood cancer.

Study objective

1. Evaluation of the variation of semen characteristics in the general population
2. Evaluation of the variance of testosterone levels in the general population

Study design

This study is an single-center, cross-sectional, observational study.

Study burden and risks

Participants will be asked to complete one questionnaire at home, which will focus on reproductive history, pubertal development and questions concerning testosterone level. This questionnaire will take about 20 minutes to complete.

In addition, participants will be asked to visit the University Medical Center Groningen (UMCG) once in order to provide one blood sample which will be collected in the morning, before 10 AM, and to provide a semen sample. The duration of the visit to the UMCG is estimated circa 90 minutes. There are no adverse events expected during the collection of semen and blood samples. The provided reference dataset of semen characteristics and testosterone levels in the general population will serve as a control group in research assessing the effects of various factors on male gonadal function, e.g. severe systemic illness (renal failure, hepatic cirrhosis, cancer), morbid obesity, exposure to toxins (alcohol, marijuana, smoking), and nutritional deficiencies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Male participants from the Lifelines cohort who are aged between 18 and 55

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years.

Exclusion criteria

Participant has been treated for cancer in the past

Participant is vasectomised

Participant had fever in the last three months

Participant works night shifts

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-06-2019

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 09-01-2019

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 26-07-2021

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64583.042.18