Semen characteristics and testosterone levels in the general population

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27729

Source
Nationaal Trial Register

Brief title
VESPER-LL

Health condition

semen analysis, fertility, testosterone
(in Dutch: semenanalyse, fertiliteit, testosteron)

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

- Semen characteristics, including volume, sperm concentration and fraction of progressive motile spermatozoa)

- Testosterone levels

Secondary outcome

Not applicable

Study description

Background summary

Background:

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.

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 population:

This study will include 400 male participants from the Lifelines cohort study, a prospective, populationbased cohort study examining the health and health-related behaviors, who are aged between 18 and 55 years.

Primary study parameters:

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

The study objective is to evaluate the variation of semen characteristics and testosterone levels in the general population. These age-specific reference values can be used as a control group in research in male populations in which impaired spermatogenesis and/or testosterone deficiency is studied.

Study design

Participants will complete one questionnaire at home (which will take about 20 minutes) and they will visit the clinic once in order to provide one blood and one semen sample (the duration of the visit is estimated circa 90 minutes).

Intervention

Not applicable

Contacts

Public
Radboud university medical center

Joyce Claessens

Geert Grooteplein Zuid 8

Nijmegen 6551 EA
The Netherlands
+31 (0)24 361 39 53
Scientific
Radboud university medical center

Joyce Claessens
Geert Grooteplein Zuid 8

Nijmegen 6551 EA
The Netherlands
+31 (0)24 361 39 53

Eligibility criteria

Inclusion criteria

Participants will be recruited from the Lifelines Cohort Study.

Inclusion criteria are:

1) Participant is male

2) Participant is between 18 and 55 years old

Exclusion criteria

1) Participant has been treated for cancer in the past

2) Participant is vasectomised

3) Participant had fever in the last three months

4) Participant works night shifts

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-09-2018
Enrollment:	400
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7192
NTR-old	NTR7383

Register	ID
Other	METC 18/143 ; KWF 10151 : ABR NL64583.042.18

Study results

Summary results
None