Semen characteristics and testosterone levels in the general population

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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...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27729

Bron
Nationaal Trial Register

Verkorte titel
VESPER-LL

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

motile spermatozoa)
- Testosterone levels

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Radboud university medical center

Joyce Claessens
Geert Grooteplein Zuid 8

Nijmegen 6551 EA

The Netherlands
+31 (0)24 361 39 53

Wetenschappelijk

Radboud university medical center

Joyce Claessens
Geert Grooteplein Zuid 8

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	400
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7192
NTR-old	NTR7383
Ander register	METC 18/143 ; KWF 10151 : ABR NL64583.042.18

Resultaten

Samenvatting resultaten
None