Male fertility after treatment with radioiodine for differentiated thyroid carcinoma

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON45710

Source
ToetsingOnline

Brief title
Male fertility after DTC

Condition

- Thyroid gland disorders
- Sexual function and fertility disorders

Synonym
Differentiated thyroid carcinoma, thyroid cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: UMCG Kanker Researchfonds

Intervention

Keyword: Differentiated thyroid carcinoma, Late effects, Male fertility, Radioiodine

Outcome measures

Primary outcome

The main study parameter is the semen concentration measured in the ejaculate

of the participating males.

Other main study parameters are:

- Semen quality, measured by means of the following parameters:

- Volume

- Concentration

- Motility

- Morphology

- VCM

- pH

- Serum endocrine markers:

- LH

- FSH

- FreeT

Secondary outcome

Secondary study parameters are:

- Conceived pregnancies/pregnancy complications/congenital malformations in

children

- Ongoing pregnancy (>12 weeks) and live birth rate

- Data regarding semen quality before radioiodine administration

- Serum: TSH en FT4

- Sexual health, defined by sexual satisfaction and sexual functioning,

whether or not combined with quality of life

Study description

Background summary

Little is known about the long term treatment effects of radioiodine for differentiated thyroid carcinoma (DTC) on male fertility. Transient impairment of gonadal function is observed after single/low doses of radioiodine in males treated for DTC. A dose-dependent effect of radioiodine on male fertility has been described by serveral studies. However, especially the effects of multiple/high radioiodine doses on long-term fertility remain unknown. Up to now, only relatively short-term studies with a small number of participants have been performed. The current study aims to evaluate long-term male fertility after high dose administration of radioiodine for DTC.

Study objective

By means of this study we want to make statements regarding the effects of (high dose) radioiodine on male fertility, depicted by various fertility parameters (serum endocrine markers (LH and FSH), semen analyses and (conceived) pregnancy (outcomes)). Sexual health will also be evaluated. Thereby, we want to be able to form universal recommendation regarding the management of male fertility after diagnosis of DTC.

Study design

This study is a multicenter cross-sectional study. All University Medical Centers (UMCs) in the Netherlands are willing to participate in this study. Patients will be evaluated from January 2017 to September 2019. Outpatient evaluation will consist of semen analysis, serum sampling and filling in a questionnaire. See also page 13 of the protocol.

Study burden and risks

Burden: males will undergo blood sampling (1x) and will be asked to fill out a questionnaire (1x). In addition, patients will be asked to deliver a semen sample for semen analysis (1x). We aim to schedule the examinations on the day of an outpatient clinic visit. Medical chart evaluation will be performed and does not cause any burden.

Benefits: survivors will be examined for possible late effects of radioiodine on fertility and will be informed about their health status.

Risks: The process of semen delivery and serum sampling are without additional risk for the patient, therefore, this study is without risks for participants.

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

All males (age * 18) that were diagnosed with DTC and treated with radioiodine after 2000 that are at least *2 years after their last treatment with a high cumulative dose of radioiodine (* 100 mCi) are eligible for inclusion for this study

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Use of drugs that interact with semen quality
- Use of anabolic steroids
- Fever (body temperature >38°C) in the three months before semen analysis
- Gonadal/testicular diseases or treatments that are associated with impairment of semen quality
- Active disease state (widespread metastases, under active treatment for DTC or active treatment with systemic therapy/radiotherapy).
- Attained age older than 60 years.
- I-131 only administered combined with use of recombinant human TSH (rhTSH) and no thyroid hormone withdrawal therapy before I-131 administrations;
- Non-compliance of thyroid hormone substitution, resulting in several measurements of TSH >10 mU/l in the last year before evaluation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2017

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-07-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2017
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	NL59401.042.16