

Mannelijke vruchtbaarheid na een hoge dosis radioactief jodium voor de behandeling van gedifferentieerd schildklierkanker

Gepubliceerd: 09-05-2017 Laatste bijgewerkt: 15-05-2024

Male fertility is possibly impaired after treatment for differentiated thyroid carcinoma with a high dose of radioactive iodine

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23189

Bron

Nationaal Trial Register

Verkorte titel

MATTER

Aandoening

Differentiated thyroid cancer (DTC/Gedifferentieerd schildkliercarcinoom

Male fertility/Mannelijke fertiliteit

Radioactive iodine/Radioactief jodium

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: UMCG Kanker Researchfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Semen concentration

Toelichting onderzoek

Achtergrond van het onderzoek

Little is known about the long term treatment effects of radioiodine for differentiated thyroid carcinoma (DTC) on male fertility. This study is a multicenter cross-sectional study. All University Medical Centers (UMCs) in the Netherlands are participating in this study. By means of this study we want to evaluate whether male fertility is impaired after treatment with radioiodine for DTC. All males (≥ 18 y) that were diagnosed with DTC and treated with a high cumulative dose of radioiodine (> 100 mCi/3.7 GBq) from 2008, at least ≥ 2 years after last administration of radioiodine are eligible for inclusion.

Evaluation consists of semen analysis, evaluation of levels of LH, FSH and free T and a questionnaire regarding fertility and sexuality.

Doel van het onderzoek

Male fertility is possibly impaired after treatment for differentiated thyroid carcinoma with a high dosis of radioactive iodine

Onderzoeksopzet

1

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All males (age ≥ 18 y) diagnosed with DTC in the Netherlands from January 2008 that are at least ≥ 2 years after their last treatment with a high cumulative dose of radioiodine (≥ 100 mCi/3.7 GBq) are eligible for inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 (i.e. testosterone suppletion, chemotherapy);
- Use of anabolic steroids;
- Fever (body temperature $>38.5^{\circ}\text{C}$) 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;
- or
- Non-compliance of thyroid hormone substitution, resulting in several measurements of TSH >10 mU/l in the last year before evaluation.

Onderzoeksopzet

Opzet

Type: Observatieonderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 15-05-2017
Aantal proefpersonen: 100
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 09-05-2017
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45389

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5966
NTR-old	NTR6332
CCMO	NL59838.042.16
OMON	NL-OMON45389

Resultaten