Does hypothyroidism induced by thyroid hormone withdrawal lead to permanent modifications of the DNA?

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Thyroid hormone withdrawal leads to permanent DNA modifications that are not seen in patients treated with rhTSH.

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

Samenvatting

ID

NL-OMON20919

Bron
NTR

Verkorte titel
Epigenetic DNA modifications due to hypothyroidism

Aandoening

Patients with differentiated thyroid cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Genzyme Europe B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction
Hypothyroidism is one of the most common endocrine disorders. Despite adequate restoration of euthyroidism with LT4, a substantial part of patients (~10-15%) display significant impairment of psychological well-being compared to matched controls. The same holds true for patients who have been treated for differentiated thyroid cancer (DTC). We speculate that the decreased QoL in DTC patients is due to the episode of hypothyroidism, induced by thyroid hormone withdrawal. Epigenetic modifications of the DNA of patients with a history of hypothyroidism are likely to affect thyroid hormone signaling for the rest of their lifes.

Objective
To study if thyroid hormone withdrawal leads to permanent DNA modifications that are not seen in patients treated with recombinant human (rh)TSH.

Study Design
Within our Academic Center for Thyroid Diseases, we are prospectively collecting repeated DNA and serum of patients treated with DTC before, during and after treatment with radioactive iodine, either augmented via thyroid hormone withdrawal or rhTSH. We will study if DNA methylation is affected by thyroid hormone withdrawal in genomic DNA of these patients, and if these changes persist after LT4 supplementation. Patients treated with rhTSH will be used as a control, since these patients undergo the same surgery and treatment with radioactive iodine, but do not become hypothyroid

Study Population
Patients, aged 18-80 years, treated with DTC before, during and after treatment with radioactive iodine, either augmented via thyroid hormone withdrawal or rhTSH.

Primary Endpoint
Epigenetic DNA modifications (does thyroid hormone withdrawal result in epigenetic modifications, and if so, do these epigenetic modifications persist after restoring euthyroidism?).

Anticipated Result
Thyroid hormone withdrawal leads to permanent epigenetic DNA modifications that are not seen in patients treated with rhTSH.

Doel van het onderzoek

Thyroid hormone withdrawal leads to permanent DNA modifications that are not seen in

patients treated with rhTSH.

Onderzoeksopzet

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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Have the capacity to understand and willingness to sign an informed consent form
2. Planned for total thyroidectomy because of differentiated thyroid cancer
3. Aged 18-80 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Alcohol abuse
2. Other malignancy
3. Clinically relevant active systemic disease (such as autoimmune or infectious diseases)
4. Pregnancy
5. Use drugs interfering with thyroid hormone metabolism (e.g. antiepileptic drugs,

amiodarone,
and lithium)
6. Other primary thyroid disease

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	30-07-2019
Soort:	Eerste indiening

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	NL7914
Ander register	METC Erasmus MC. : MEC-2012-561

Resultaten