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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20919

Source NTR

Brief title Epigenetic DNA modifications due to hypothyroidism

Health condition

Patients with differentiated thyroid cancer

Sponsors and support

Primary sponsor: Erasmus MC **Source(s) of monetary or material Support:** Genzyme Europe B.V.

Intervention

Outcome measures

Primary outcome

Epigenetic DNA modifications

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n/a

Study description

Background summary

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.

Study objective

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

Study design

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Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)

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Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	20
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date: Application type:

30-07-2019 First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7914
Other	METC Erasmus MC. : MEC-2012-561

Study results