

# cycling from hypoThyroidism to Hyperthyroidism during Early treatment of differentiated Thyroid carcinoma

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We hypothesize that quick cycling from hypothyroidism to hyperthyroidism in early treatment of DTC has deleterious effects on cardiac function.

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

## Samenvatting

### ID

NL-OMON25756

### Bron

Nationaal Trial Register

### Verkorte titel

THETA

### Aandoening

Differentiated thyroid carcinoma

### Ondersteuning

**Primaire sponsor:** University Medical Center Groningen

**Overige ondersteuning:** self-financing

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

### Primaire uitkomstmaten

To compare the effects of hypothyroidism and hyperthyroidism on cardiac left ventricular

function, as assessed by CMR, in subjects with differentiated thyroid cancer during their early treatment.

## Toelichting onderzoek

### Achtergrond van het onderzoek

The THETA-study is a longitudinal observational study in patients with differentiated thyroid carcinoma. The primary objective is to compare the effects of hypothyroidism and hyperthyroidism on cardiovascular function.

### Doel van het onderzoek

We hypothesize that quick cycling from hypothyroidism to hyperthyroidism in early treatment of DTC has deleterious effects on cardiac function.

### Onderzoeksopzet

The study will have three main visits, the first visit will be combined with the hospitalisation for regular iodine treatment. The screening visit takes place before radioiodine ablation therapy. Subjects will subsequently be invited at week 0, 10, and 20. Patients with a DTC diagnosis after hemithyroidectomy will be asked to participate in a baseline visit. This visit takes place after hemithyroidectomy and before total thyroidectomy, during euthyroidism.

### Onderzoeksproduct en/of interventie

None

## Contactpersonen

### Publiek

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## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The subject has a histologically confirmed diagnosis of DTC.

The subject is at least 18 years old.

The subject has written informed consent

The subject is mentally competent (according to the criteria mentioned in *Wet Geneeskundige Geneeskunde (Wet Geneeskundige Geneeskunde) boek 2, bijlage 9*)

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

„h The subject is 75 years or older.

„h The subject will receive treatment with rhTSH before radioiodine ablation therapy.

„h The subject has a history of severe lung disease (COPD gold class III or worse).

„h The subject has a history of cerebrovascular or coronary events.

„h The subject has a history of atrial fibrillation.

„h The subject has a history of heart failure NYHA class III or worse.

„h The subject has a severe limited physical strain (NYHA class IV)

„h The subject is unable or not willing to sign informed consent.

„h The subject is pregnant

„h The subject has contra-indications for MRI, defined as severe claustrophobia, having an implantable cardioverter-defibrillator, known allergy for gadolinium, known renal dysfunction with eGFR <30, treated with haemodialysis, or body weight >200 kg.

For the secondary objective cholesterol function and balance, subjects who meets any of the following criteria will be excluded from participation in this sub-study.

„h The subject uses lipid lowering medication

„h The subjects uses laxatives

For subjects participating in the baseline measurements:

„h The subject uses thyroid hormone medication

## Onderzoeksopzet

### Opzet

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

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies

Datum: 01-08-2018

Soort:

Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43803

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL7228
NTR-old	NTR7427
CCMO	NL52832.042.15
OMON	NL-OMON43803

## Resultaten