REduction of LEvothyroxine in Adults; a SElf controlled study

Gepubliceerd: 22-08-2019 Laatst bijgewerkt: 15-05-2024

At least 50% of older patients using levothyroxine treatment can be withdrawn successfully and safely.

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

Samenvatting

ID

NL-OMON24126

Bron
NTR

Verkorte titel
RELEASE

Aandoening

Hypothyrodism

Ondersteuning

Primaire sponsor: ZonMW HGOG
Overige ondersteuning: ZonMW HGOG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the proportion of participants that withdraw their thyroid medication successfully, defined as normal fT4 levels and TSH levels <10 mU/L, at 52 weeks after start of the discontinuation of levothyroxine.

Toelichting onderzoek

Achtergrond van het onderzoek

Many older persons in the Netherlands use levothyroxine (2015: >215.000 aged 65+), and often have been using levothyroxine for a very long time. Initial indications for treatment are often not well registered, inaccurate or even inappropriate due to changing guidelines. Currently, levothyroxine treatment is indicated for patients with overt hypothyroidism (high Thyroid Stimulating Hormone [TSH], low free Thyroxin [fT4]). For subclinical hypothyroidism (high TSH, normal fT4), the most common thyroid disorder in older people (3-18% aged 65+), guidelines vary. Recently, in the TRUST trial, it was shown that levothyroxine treatment was not clinically beneficial in people aged 65 years and older with subclinical hypothyroidism. Given the high prevalence of levothyroxine use, the ambiguous treatment indications, the lack of evidence for beneficial effects of treatment and the health risks associated with (over)treatment, we hypothesize that discontinuation of levothyroxine is feasible in many older persons without negative consequences.
An self-controlled observational study will be performed investigating the stepwise reduction of levothyroxine treatment in persons aged 60 years and older. The primary aim is to study what proportion of participants that withdraw their levothyroxine successfully, defined as having normal fT4 levels and TSH levels <10 mU/L at 52 weeks after start of the discontinuation.

Doel van het onderzoek

At least 50% of older patients using levothyroxine treatment can be withdrawn successfully and safely.

Onderzoeksopzet

Run-in period (from t = -12 weeks): baseline measurement of thyroid function (TSH and fT4), questionnaires, continuation of levothyroxine treatment.
Discontinuation phase (from t = 0 weeks): stepwise reduction of levothyroxine based on measurements of TSH and fT4; questionnaires.
Follow-up phase: measurement of thyroid function and questionnaires.

Onderzoeksproduct en/of interventie

Stepwise reduction of levothyroxine treatment.

Contactpersonen

Publiek

Leiden University Medical Center - Department of Public Health and Primary Care
Rosalinde Poortvliet

0715268444

Wetenschappelijk

Leiden University Medical Center - Department of Public Health and Primary Care
Rosalinde Poortvliet

0715268444

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) Aged 60 years or over (≥ 60 years)
2) Using any levothyroxine mono-therapy medicament (ATC: H03AA01) continuously for a minimum of 1 year with stable dose of levothyroxine.

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:
1) Last measurement of TSH ≥10 mU/L during levothyroxine treatment
2) Current reason for levothyroxine treatment: patients with history of thyroidectomy; radioactive iodine treatment or neck irradiation; congenital hypothyroidism; secondary hypothyroidism, or concurrent amiodarone or lithium use
3) Dose of treatment; for safety issues, patients using > 150 mcg levothyroxine per day (0.48%) will not be eligible
4) Diagnosis of heart failure NYHA grade IV
5) Participation in ongoing trials of therapeutic interventions
6) Life-expectancy of less than 6 months
7) Diagnosis of dementia
8) Incapacitated adults
9) Persons that plan to move out of the region in which the study is being conducted in the

next months.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-08-2019
Aantal proefpersonen:	360
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52395
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7978
CCMO	NL69753.058.19
OMON	NL-OMON52395

Resultaten