REduction of LEvothyroxine in Adults; a SElf controlled study

No registrations found.

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

Summary

ID

NL-OMON24126

Source
NTR

Brief title
RELEASE

Health condition

Hypothyrodism

Sponsors and support

Primary sponsor: ZonMW HGOG
Source(s) of monetary or material Support: ZonMW HGOG

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Effects of discontinuing levothyroxine on thyroid-related quality of life including somatic, psychological and social domains; general health; treatment satisfaction for medication; daily functioning.
The proportion of levothyroxine users who can achieve a substantial dose lowering of their levothyroxine dose after one year.
Demographic, clincal characteristics and attitudes towards discontinuation of those levothyroxine users aged 60 years and older willing to discontinue levothyroxine treatment and those successfully reducing their dosage.
Characteristics of persons aged 60 years and older that physicians consider safe to withdraw thyroid medication from, and medical reasons not to discontinue treatment. Frequency of discontinuation (or stepping-down) levothyroxine treatment by general practitioners in usual care .
Physicians' experience on the recruitment of patients and the consultations.
Study participants' experience of discontinuation of medication.

Study description

Background summary

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.

Study objective

At least 50% of older patients using levothyroxine treatment can be withdrawn successfully and safely.

Study design

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.

Intervention

Stepwise reduction of levothyroxine treatment.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2019
Enrollment:	360
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-08-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52395
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results