Improvement of laboratory diagnostics in hypothyroid patients using levothyroxine.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON53877

Source
ToetsingOnline

Brief title
ANTICIPATE

Condition

- Thyroid gland disorders

Synonym
hypothyroidism, slow acting thyroid

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: uit de reserves van de afdeling

Intervention

Keyword: hypothyroidism, laboratory measurements, levothyroxine

Outcome measures

Primary outcome

fT3, fT3/fT4 ratio and fT4 and TSH concentrations.

Secondary outcome

- Laboratory tests: rT3, TT4, TT3, SHBG, acylcarnitine profile, tyrosine,

phenylalanine, serine and DIO1/2/3 polymorphisms

- Questionnaire: ThyPRO-39

Study description

Background summary

Hypothyroidism is a common disorder in the Netherlands. Patients with hypothyroidism have a deficiency of thyroid hormones in blood and tissues and are treated with thyroid hormone (T4 or levothyroxine). T4 is a prohormone that is converted to T3, the active hormone, in the tissues. The effect of T4 treatment is monitored by measuring thyroid hormones in the blood (TSH and/or fT4). TSH is produced by the pituitary based on the circulating thyroid hormone concentrations and is seen as a good reflection of thyroid hormone status. Despite TSH and fT4 concentrations within the reference intervals, a part of the patients still experience discomfort. Moreover, fT4 does not appear to be the most suitable parameter in all cases for measuring thyroid hormone status in patients taking levothyroxine. However, a better alternative has not yet been implemented. In a small group of patients, TSH measurement cannot be relied upon because of the cause of hypothyroidism, and, therefore, fT4 is the most important marker to assess thyroid hormone status.

Study objective

The aim of this study is to identify whether we can improve laboratory diagnostics in patients with hypothyroidism receiving thyroid hormone supplementation. We will investigate whether, in addition to the current laboratory tests of TSH and fT4, other already available laboratory tests provide better insight into the thyroid hormone status of the patient.

Alternatives could be fT3 and the derived fT3/fT4 ratio. If these measurements better reflect patient well-being in relation to thyroid hormone status, this will particularly benefit the follow-up of patients taking L-T4 in whom TSH cannot be used to monitor thyroid hormone status (such as patients with central hypothyroidism).

Study design

Cross-sectional study design

Study burden and risks

- Venous blood sampling. In healthy controls, we will draw 20 mL of blood. The risks are negligible and are limited to the development of a hematoma due to the venipuncture.
- Additional venous blood sampling. In the study, we will draw 20 mL of blood in addition to regular blood draw due to clinical purposes. There are no risks involved, since the blood is collected for clinical purposes and the additional collection of 20mL of blood does not have any risks or consequences. Furthermore, results that are measured extra cannot present deviant outcomes that lead to further research.
- Completion of questionnaire (ThyPRO-39). In the study, participants complete a one-time brief questionnaire about the impact of their thyroid disorder on their daily lives. Participants may experience a small psychological burden when completing the questionnaire if their thyroid disorder negatively affects their lives. However, the questionnaire is completed only once and by using the short version, participants are unlikely to experience any difficulties.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hypothyroid patients
- Ability to provide informed consent;
- Ability to speak and understand Dutch or English
- Intake of a stable dose of levothyroxine, meaning the dosage of levothyroxine must not be changed during the appointment at the outpatient clinic
- Diagnosis of one of these forms of hypothyroidism
O Patients with primary hypothyroidism: euthyroid based on TSH according to physician
O Patients with hypothyroidism after a total thyroidectomy due to thyroid carcinoma (therefore athyroid): on target TSH according to physician (target TSH depending on stage/severity of carcinoma)
O Patients using L-T4 due to therapy of Graves* disease: euthyroid based on TSH according to physician (TSH cannot be suppressed, namely TSH within reference interval of 0,5-5,0 mU/L)
O Patients with central hypothyroidism: euthyroid based on fT4 according to physician (common is fT4 in the upper limit, reference interval is 12-22 pmol/L)

Healthy controls
- Ability to provide informed consent;
- Ability to speak and understand Dutch or English
- Consider themselves healthy

Exclusion criteria

Hypothyroid patients
- Not euthyroid according to physician
- Pregnant

- Patients using L-T4 due to the treatment of Graves* disease: if TSH is still suppressed
- Any of the following medication
o Iodide
o Liothyronine (Cytomel)
o Oral anticonceptiva
o Active treatment of malignancy (except DTC)

Healthy controls
- Pregnancy
- Any of the following medication
o Thyroid medication (a.o. levothyroxine, thiamazol, PTU)
o Lithium
o Amiodarone
o Propranolol
o Iodide
o Glucocorticoids
o Oral contraceptives
o Heparin
o Growth hormone
o Active treatment of malignancy

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2022
Enrollment:	500
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL81578.018.22