The effect of a self controlled dose of Levothyroxine on the quality of life and thyroid stimulating hormone in patients treated for hypothyroidism: a randomized, double blind, consecutive study.

Published: 05-07-2011
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON36807

Source
ToetsingOnline

Brief title
Self controlled dose of Thyrax and QoL in patients with hypothyroidism.

Condition

- Thyroid gland disorders

Synonym
slow-acting thyroid gland

Research involving

Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: maasstad ziekenhuis

Intervention

Keyword: Hypothyroidism, Levothyroxine, Quality of life, Self-controlled dose

Outcome measures

Primary outcome

Primary endpoint: QoL by SF/RAND 36.

Thereby: Symptoms and complaints by symtomlist hypothyroidism, general symptom

list and Hospital anxiety and depression scale.

TSH,T4 and T3.

Secondary outcome

Secondary endpoints:

Influence of BMI on QoL. Clinical parameters like heartbeat, blood pressure and

laboratory findings.

Study description

Background summary

Hypothyroidism is a chronical disease with a bad influence on quality of life in this patients. Some researchers mean that self control in treatment and medication is a potential good development that can improve medical condition, make patients stronger and can positively influence attitude and behaviour. Our hypothesis is that when patients can have influence on their dose of Levothyroxine, this will have a positive influence on their quality of life. It is also interesting what the role of placebo effect in this situation will be.

Study objective

The goal of this study is to positively influence quality of life in patients with hypothyroidism by giving them back control in their treatment. We also want to see what the placebo effect will be. And at last we want to check if patients have the urge to lower their TSH levels if they can choose their own dose of Levothyroxine and if that has a relationship with their quality of life.

Study design

A randomized, double blind, consecutive study on the outpatient clinic at the department of internal medicine and endocrinology of the Maasstad Hospital Rotterdam. Patients treated with Levothyroxine because of primary hypothyroidism will be included.

Intervention

Patients who are not content about the treatment of their hypothyroidism with Levothyroxine get the chance to controle their own dose. There will be 2 moments during the study where they can decide if they want to raise their dose of Levothyroxine. At the first time of choice randomization will follow and the first half of the group will get 25 mcg extra Levothyroxine and the other half will receive a placebo. After 6 weeks of treatment the placebo group will also receive 25 mcg extra medication. So after 12 weeks the whole group has been treated with 25 mcg extra Levohyroxine. At the second moment of choice patients can either go back to their original dose, stay at 25 mcg extra or decide they want another 25 mcg extra. There will be another randomization in group that wants extra medication. Half will get extra 25 mcg extra and half will get an placebo.

Study burden and risks

The risk of this intervention is small because this patients use Levothyroxine for at least 6 months. This medication is also the first choice of treatment in hypothyroidism for a very long time and the maximal raise is 50 mcg. In fact this is te normal way of raise in the outpatient clinic, only a bit faster and patients have a state of euthyroidism. We think this raise will not give any problems.

Contacts

Public
Maasstadziekenhuis

Groene Hilledijk 315

3075 EA Rotterdam
NL
Scientific
Maasstadziekenhuis

Groene Hilledijk 315
3075 EA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Primary Hypothyroidism
- Euthyroidism
- Stable dose of Levothyroxine for over 6 months
- Age 18-75
- Own wish to change dose of medication

Exclusion criteria

Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-07-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29339
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35082.101.11
Other	volgt nog
OMON	NL-OMON29339