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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29339

Source
NTR

Brief title
Patients in control of Thyrax

Health condition

Self-controlled dose
Levothyroxine
Quality of life
Hypothyroidism

Zelf-gecontroleerde dosis
Levothyroxine
Kwaliteit van leven
Hypothyreoidie

Sponsors and support

Primary sponsor: Maasstad Ziekenhuis Rotterdam
Source(s) of monetary or material Support: Maasstad Ziekenhuis Rotterdam

Intervention

Outcome measures

Primary outcome

1. QoL by SF/RAND 36;

2. Symptoms and complaints by symptomlist hypothyroidism;

3. General symptom list and Hospital anxiety and depression scale;

4. TSH,T4 and T3.

Secondary outcome

1. Influence of BMI on QoL;

2. Clinical parameters like heartbeat, blood pressure and laboratory findings.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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.

Study population:

Patients who visit the outpatient clinic of the department of internal medicine because of primary hypothyreoidism. There will have to be a state of euthyroidim and they have to use a stable dose of Levothyroxine for over more than 6 months without side effects.

Study objective

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 design

T = 0, 6, 12 and 18 months.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary Hypothyroidism;

2. Euthyroidism;

3. Stable dose of Levothyroxine for over 6 months;

4. Age 18-75;

5. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36807
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2675
NTR-old	NTR2803
CCMO	NL35082.101.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36807

Study results

Summary results
N/A