Evening versus Morning Administration of Levothyroxine: a randomised controlled double-blind trial

No registrations found.

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

Summary

ID

NL-OMON26022

Source
Nationaal Trial Register

Health condition

hypothyroidism, bedtime levothyroxine, quality of life
Hypothyroidism --> hypothyreoidie
Bedtime levothyroxine --> inname levothyroxine voor het slapengaan

Sponsors and support

Primary sponsor: Medisch Centrum Rijnmond-Zuid
Source(s) of monetary or material Support: Van Puyvelde Fonds (private fund)

Intervention

Outcome measures

Primary outcome

Significant change in TSH and thyroid hormones FT4/T3

Secondary outcome

1 Change in:
a. blood pressure;
b. pulse;
c. weight;
d. other lab results (creatinine, lipids);
2. Change in quality of life;
3. Symptoms of hypo-or hyperthyroidism.

Study description

Background summary

Hypothyroid patients worldwide are advised to take levothyroxine tablets in the morning half an hour before breakfast. This is because a fiber-enriched diet and ingestion of certain drugs have been shown to have an adverse effect on the intestinal absorption of levothyroxine. In a recent study we showed that TSH significantly decreased and T4 and T3 significantly increased after changing the administration time of levothyroxine from morning to the evening, at bedtime.
We want to perform a large randomised double blind study among patients with hypothyroidism. In this study patients will be asked to take a capsule in the morning as well as in the evening, with one of these capsules containing levothyroxine and the other capsule being a placebo. The patient and his/her doctor will not know which capsule contains the actual levothyroxine. The hospital pharmacist will perform the randomisation. After 3 months the capsules will be switched, so that the capsule containing levothyroxine is taken at a different moment of the day. Every 6 weeks patients will return to the outpatient department for a check-up and bloodtest. At the start of the study and at 3 and 6 months, patients will fill out quality-of-life forms.
Primary endpoint will be a significant change in TSH and FT4/T3 after switching the administration time of levothyroxine to bedtime. Secondary endpoints will be a change in weight, bloodpressure, pulse frequency and change in quality of life.

Study objective

Administration of levothyroxine at bedtime significantly changes TSH and thyroid hormone levels compared to morning administration. Quality of life will improve with bedtime administration

Intervention

During the study, patients will have to take 2 tablets a day (one in the morning and one at bedtime), instead of 1 tablet. One of the tablets is levothyroxine, the other placebo. After 3 months the tablets will be switched. During these 24 weeks the patients will return to the outpatient department five times for a check-up, and bloodsamples will be taken

Contacts

Public
Medisch Centrum Rijnmond Zuid,
Afdeling Interne Geneeskunde
A. Berghout
Rotterdam
The Netherlands
+31 10-2911911
Scientific
Medisch Centrum Rijnmond Zuid,
Afdeling Interne Geneeskunde
A. Berghout
Rotterdam
The Netherlands
+31 10-2911911

Eligibility criteria

Inclusion criteria

1. Patients with primary hypothyroidism;
2. Above the age of 18 years old;
3. On a stable regimen of levothyroxine for at least 6 months.

Exclusion criteria

1. Pregnancy;
2. Disease of the stomach;
3. Jejunum or ileum;
4. Use of medication known to interfere with the uptake of levothyroxine

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-04-2007
Application type:	First submission

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
NTR-new	NL934
NTR-old	NTR959
Other	: 2006/45
ISRCTN	ISRCTN17436693

Study results

Summary results

Clin Endocrinol (Oxf). 2007 Jan;66(1):43-8

Effects of evening vs morning thyroxine ingestion on serum thyroid hormone profiles in hypothyroid patients.Bolk N, Visser TJ, Kalsbeek A, van Domburg RT, Berghout A.