

Evening versus morning administration of levothyroxine

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A. Berghout

Contact details
Medisch Centrum Rijnmond Zuid
Afdeling Interne Geneeskunde
Rotterdam
Netherlands
-
+31 (0)10 2911911
berghouta@mcrz.nl

Additional identifiers

Protocol serial number
2006/45

Study information

Scientific Title
Evening versus morning administration of levothyroxine: a randomised controlled double-blind trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, double blinded, placebo controlled, crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypothyroidism, bedtime levothyroxine, quality of life

Interventions

During the study, patients will have to take two tablets a day (one in the morning and one at bedtime), instead of one tablet. One of the tablets is levothyroxine, the other placebo. After three 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 blood samples will be taken.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levothyroxine

Primary outcome(s)

Significant change in TSH and thyroid hormones Free Thyroxine (FT4)/Free Triiodothyronine (FT3).

Key secondary outcome(s)

1 Change in:

1.1. Blood pressure

1.2. Pulse

1.3. Weight

1.4. Other lab results (creatinine, lipids)

2. Change in quality of life

3. Symptoms of hypo-or hyperthyroidism

Completion date

01/05/2008

Eligibility

Key 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 six months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Pregnancy
2. Disease of the stomach, jejunum or ileum
3. Use of medication known to interfere with the uptake of levothyroxine

Date of first enrolment

01/05/2007

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Medisch Centrum Rijnmond Zuid

Rotterdam

Netherlands

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Sponsor information

Organisation

Medical Centre Rijnmond-Zuid (MCRZ) (The Netherlands)

ROR

<https://ror.org/01n0rnc91>

Funder(s)

Funder type

Not defined

Funder Name

Van Puyvelde Fonds (from private funds)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	01/01/2007		Yes	No
Results article	main trial results	13/12/2010		Yes	No