Evening versus morning administration of levothyroxine

| Submission date | Recruitment status | Prospectively registered | | |
|-------------------|-----------------------------------|--|--|--|
| 30/05/2007 | No longer recruiting | ☐ Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 30/05/2007 | Completed | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 03/10/2017 | Nutritional, Metabolic, Endocrine | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers 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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

- 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

Overall study start date

01/05/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

100

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)

Sponsor details

Groene Hilledijk 315 Rotterdam Netherlands 3075

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01n0rnc91

Funder(s)

Funder type

Not defined

Funder Name

Van Puyvelde Fonds (from private funds)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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 |