ISRCTN17436693 https://doi.org/10.1186/ISRCTN17436693

Evening versus morning administration of levothyroxine

Submission date	Recruitment status
30/05/2007	No longer recruiting
Registration date	**Overall study status**
30/05/2007	Completed
Last Edited	**Condition category**
03/10/2017	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.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