Oral Thyroid hormone In Healthy volunteers Study: an interventional study on the effect of thyroid hormone on coagulation and fibrinolytic parameters.

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Primary objective:- To define the overall effect of oral Levothyroxine on coagulation parameters.Secondary objectives:- To define the specific effect of Levothyroxine on each tested coagulation parameters.- To define the specific effect of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON31212

Source
ToetsingOnline

Brief title
OTIHS

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Thyroid gland disorders

Synonym
coagulation system, excess of thyroid hormone, hemostasis, hyperthyroidism

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: vanuit geld voor onderzoek binnen de afdeling interne geneeskunde van het Slotervaart Ziekenhuis en de afdeling vasculaire geneeskunde van het AMC.

Intervention

Keyword: Coagulation, Fibrinolysis, Levothyroxine, Thyroid hormone

Outcome measures

Primary outcome

Coagulation and fibrinolytic parameters:

1) Prothrombin fragment 1+2 (F1+2)

2) Von Willebrand factor antigen (vWfAg)

3) D-dimer (ELISA assay)

4) Prothrombin time (PT)

5) Activated partial thromboplastin time (aPTT)

6) von Willebrand factor activity

7) factor VIII:C

8) Plasmin-antiplasmin complex (PAP)

9) Thrombin generation test (ETP)

Secondary outcome

Lipid parameters:

1) Total cholesterol

2) Low density lipoprotein (LDL)

3) High density lipoprotein (HDL)

4) Lipoprotein (a) (Lp(a))

5) Apolipoprotein A-I (Apo A-I)

6) Apolipoprotein B (Apo B)

7) CRP (C-Reactive protein)

Study description

Background summary

The link between the haemostatic system and thyroid disease has been investigated since the beginning of the last century. Several mechanisms are involved at different levels. Both thyroid dysfunction and autoimmunity may modify physiological processes of primary and secondary haemostasis and lead to bleeding or thrombosis. In particular, the influence on the coagulation system is mainly mediated by the interaction between thyroid hormone and its receptors.
In in vivo studies, several coagulation abnormalities have been reported in patients with hypothyroidism and hyperthyroidism. Unfortunately, most published studies on the relation between the coagulation system and thyroid hormones have important methodological drawbacks. Lack of a control group, small study size, heterogeneity of cause and of severity of thyroid dysfunction, and different laboratory assays obscures the real in vivo effects of elevated and decreased thyroid hormones on the hemostatic system.
To definitely define the overall in vivo effect of thyroid hormones on the coagulation system, we plan this interventional trial on healthy volunteers.

Study objective

Primary objective:
- To define the overall effect of oral Levothyroxine on coagulation parameters.

Secondary objectives:
- To define the specific effect of Levothyroxine on each tested coagulation parameters.
- To define the specific effect of Levothyroxine on each tested lipid parameters.

Study design

Single blinded randomised controlled cross-over trial.

Intervention

Levothyroxine 0,3 mg per day for 14 days.

Study burden and risks

Burden associated with study participation:
- six hospital visits for blood sampling, minimal physical examination, ECG and a short history of symptoms and signs.
- Use of study medication for 14 days.

Risks associated with participation:
The use of Levothyroxine can cause symptoms associated with (mild) hyperthyroidism. There is a small risk of development of thyrotoxicosis with cardiac arythmias. However, during each hospital visit (every 7 days) an ECG will be made and any occuring signs and symptoms will be evaluated to check heart frequency, heart rythm and the severity of hyperthyroidism. Because of these frequent controls, any risks associated with the use of study medication will be minimised.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adult >= 18 years and <= 40 years old.
- Informed consent.

Exclusion criteria

- Long term drug therapy including use or oral anticonceptive agents.
- Ongoing febrile, inflammatory, cardiovascular, renal, pulmonary, liver, neurological, endocrine, neoplastic diseases.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL17151.048.07