Hypo vWf: hypothyroidism and Von Willebrand factor.

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This observational cohort study is designed to evaluate the prevalence of acquired von Willebrand*s syndrome in patients with a new diagnosis of overt hypothyroidism.

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

Summary

ID

NL-OMON30758

Source
ToetsingOnline

Brief title
Hypo vWf

Condition

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

Synonym
coagulation disorder, Hypothyroidism: underactive thyroid gland, low levels of thyroid hormone. Acquired von Willebrand syndrome: clotting protein deficiency

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;Slotervaart Ziekenhuis en de afdeling vasculaire geneeskunde;AMC

Intervention

Keyword: Hypothyroidism, Von Willebrand factor

Outcome measures

Primary outcome

von Willebrand factor antigen and activity (ristocetin cofactor), multimer

pattern, factor VIII activity, and PFA-100, TSH, fT4, Hb, platelets, creatinin.

Secondary outcome

Bleeding history.

Study description

Background summary

Patients with overt hypothyroidism may present with abnormal bleeding, often manifest as menorrhagia or easy bruising. In many instances the laboratory features are compatible with an acquired von Willebrand*s syndrome, type 1. These have been shown to be reversible with L-thyroxine treatment. Even if a lot of case reports have been published, the frequency of acquired von Willebrand*s syndrome in hypothyroidism is still unknown, such as the prevalence of bleeding episodes.

Study objective

This observational cohort study is designed to evaluate the prevalence of acquired von Willebrand*s syndrome in patients with a new diagnosis of overt hypothyroidism.

Study design

Observational, cohort study.
Consecutive patients with a new diagnosis of primary overt hypothyroidism identified in three teaching hospitals: Ospedale di Circolo, Varese, Italy; Slotervaart Hospital, Amsterdam, The Netherlands; Academic Medical Center, Amsterdam, The Netherlands.

Study burden and risks

Two blood samples and a bleeding history are considered as a low burden and of a minimally invasive nature. Except for a chance of haematoma development at the site of puncture, no extra risks are involved.

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

1. 18 years or older, regardless of sex and race AND
2. Patients with a new diagnosis of primary overt hypothyroidism, before or within the first 48 hours of replacement therapy. Patients with autoimmune primary hypothyroidism will be enrolled in each hospital as the main population group.
Also patients with temporary hypothyroidism will be enrolled as a subgroup population.

Exclusion criteria

a. Secondary hypothyroidism
b. Subclinical hypothryroidism
c. Thyroid hormone replacement therapy > 48 hours at inclusion
d. Known congenital or acquired von Willebrand syndrome
e. Presence of a severe inflammatory disease (e.g. active inflammatory bowel disease, pneumonia)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	200
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	NL16353.048.07