Coagulation and fibrinolysis in hyperparathyroidism secondary to Vitamin D Deficiency: the CoViDD study

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Aim of our study is to investigate the influence of HPT secondary to moderate-severe vitamin D deficiency and vitamin D replacement on the coagulation and fibrinolysis system

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38482

Source
ToetsingOnline

Brief title
CoViDD study

Condition

- Other condition
- Parathyroid gland disorders
- Vitamin related disorders

Synonym
hyperparathyroidism secondary to Vitamin D Deficiency, overactivity of the parathyroids because of a shortage of vitamin D

Health condition

cardiovasculaire aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: via de SKWOSZ (stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis

Intervention

Keyword: coagulation, fibrinolysis, secondary hyperparathyroidism, vitamin D deficiency

Outcome measures

Primary outcome

The following groups of lab markers will be tested:

- Overall test: vit. D level, PTH, serum calcium, phosphate, creatinin,

albumin, hsCRP

- Coagulation markers: von Willebrand factor and ristocetin activity, FVIII,

FVII, FIX, FX, FXI, fibrinogen, thrombin

- Natural anticoagulant inhibitors: antithrombin, protein C, protein S

- Fibrinolysis markers: t-PA, PAI-1, TAFI, D-dimer

Secondary outcome

nvt

Study description

Background summary

Endocrine disorders can influence the hemostatic balance. Abnormal coagulation test results have been observed in patients with abnormal hormone levels. An effect on markers of coagulation and fibrinolysis has been hypothesized also for hyperparathyroidism (HPT). Primary HPT is associated with an increased

risk of cardiovascular (CV) morbidity and mortality. Many known CV risk factors, such as hypertension, endothelial dysfunction, dyslipidemia, and increased insulin resistance, have been reported in primary HPT. Few published studies suggest increased levels of factor (F) VII, FX, D-dimer, tissue plasminogen activator (t-PA) and plasminogen activator inhibitor (PAI)-1. However, results are conflicting and several methodological drawbacks limit any firm conclusion.
There is also evidence that vitamin D deficiency is an important CV risk factor or indicator. Vitamin D deficiency is the most frequent cause of secondary HPT. Therefore, HPT secondary to severe vitamin D deficiency is an optimal clinical model to investigate the influence of parathyroid hormone (PTH) and vitamin D replacement on the coagulation and fibrinolysis system.

Study objective

Aim of our study is to investigate the influence of HPT secondary to moderate-severe vitamin D deficiency and vitamin D replacement on the coagulation and fibrinolysis system

Study design

Prospective cohort study with a control group

Study burden and risks

At baseline and after 2 months, blood (30 ml) will be drawn out of a vein. The treatment of the vitamin D deficiency will not be influenced.

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

All consecutive adult patients with moderate-severe vitamin D deficiency, defined as blood levels of 25-OH-D less than 10 ng/ml (25 nmol/l). Controls: patients with vitamin D deficiency already on vitamin D suppletion with a normal PTH and vitamin D

Exclusion criteria

Pregnancy, acute and chronic renal disease, liver cirrhosis, granulomatosis, primary hyperparathyroidism, malabsorption syndromes, Von Willebrand disease, haemophilia, recent bariatric surgery (<13 months before vitamin D deficiency diagnosis)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2013
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	NL45045.048.13