Evaluation of FGF-23 suppressibility by Calcitonin in Healthy Men- pilot study

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In this studie we wish to examine the FGF-23 suppressive effects of calcitonin in healthy men.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32168

Source
ToetsingOnline

Brief title
FGF-23 suppressibility by Calcitonin

Condition

- Other condition

Synonym
phosphate homeostasis, phosphate regulation

Health condition

fysiologische regulatie fosfaat houshouding

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: eigen research fonds

Intervention

Keyword: Calcitonin, FGF-23

Outcome measures

Primary outcome

A significant change in de serum FGF-23 levels in response to a single

subcutaneous injection of calcitonin 200 IU.

Secondary outcome

De serum levels for calcium, parathormon and vitamin D.

Study description

Background summary

Fibroblast growth factor 23 (FGF-23) is a recently discovered hormone that inhibits renal tubular phosphate absorption and 1-alfa hydroxylation of vitamin D. Next to PTH it probably is the most important hormone to maintain phosphate homeostasis in man. The source of FGF-23 is not exactly known, however several data sugest that it is secreted by osteogenic cells in response to hyperphosphatemia. FGF-23 serum levels change in response to dietary phosphate loading and restriction. A negative hormonal feedback signal for FGF-23 production has not been discovered yet.

We recently discovered that calcitonin markedly suppressed FGF-23 production in a patient with tumor-induced osteomalacia caused by an FGF-23 secreting leiomyoma. Calcitonin is produced by the parafollicular cells of the thyroid gland. It has been shown to lower serum calcium and phosphate, primarily by inhibiting osteoclast-mediated bone resorption. Its exact physiological remains still unclear.

Based on our experience with calcitonin as an FGF-23 suppressive agent, we hypothesize that calcitonin may be a physiologically important regulator of FGF-23 production and secretion in healthy humans. The reported serum half life of FGF-23 varies between 21 and 57 minutes, threfore if calcitonin should have significant suppressive effects it must be detectable within a period of 8 hours.

Study objective

In this studie we wish to examine the FGF-23 suppressive effects of calcitonin in healthy men.

Study design

Double blind, placebo controlled, cross-over study.

Intervention

All subjects are examined on two occasions, once after exposure to placebo 1 ml NaCl 0.9% subcutaneously, and once following 1 ml calcitonin 200 IU/ml subcutaneously.

Study burden and risks

The burden associated with participation to the study lies mostly in the fact that the persons have to spend some time in the hospital, in total approximately 18 hours, because of the frequent bloedsampling. Furthermore the subjects will be asked to use a standard phosphate enriched diet for four days before and on the intervention day.
An allergic reaction due to subcutaneous administration of calcitonin could also be considered as a minor risk.

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

Healthy, male sex, age 20-55 years

Exclusion criteria

Serum creatinin > 100 micromol/L, or glomerular filtration rate < 80 ml/min;
Abnormal serum calcium, phosphate, albumin, vitamin D, or PTH level;
Any medication;

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	12

Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL21603.091.08