Vitamin D levels in relation to other calcium and phosphate regulating hormones in children in Murmansk and Groningen. Effect of summer and winter. A pilot study.

Published: 23-10-2019
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Objective: To obtain data to be used for designing a larger scale study on the incidence of 25OHD levels below the recommended level of 50 nmol/l in children in Murmansk, Russia and Groningen, the Netherlands.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON48435

Source
ToetsingOnline

Brief title
Vitamin D children

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym
vitamin D deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,stichting kinderendocrinologie UMCG

Intervention

Keyword: children, FGF23, minerals, vitamin D

Outcome measures

Primary outcome

Main study parameters/endpoints: The incidence of plasma 25OHD levels below 50

nmol/l in each cohort in both countries in two seasons.

Secondary outcome

Secondary study parameter(s)

The correlation between Ca, P, alkaline phosphatase, 25OHD and FGF23.

Relation between dietary and supplemental intake of Ca and vit D with plasma

25OHD levels.

Study description

Background summary

Rationale: Vitamin D (Vit D) is a vitamin that is well known for its action on bone maturation and calcification. Vit D improves the uptake of calcium in the gastro-enteral tract and the deposition in bone. A lack of vit D, but most likely a lack of both vit D and calcium, can cause nutritional rickets. Studies done over the past years have shown more effects of vit D in the human. Low levels of vit D are in children related with a higher risk on Diabetes Mellitus type 1, multiple sclerosis, Crohn*s disease and Rheumatoid arthritis, all autoimmune diseases. Recently, an effect of vit D is also shown on other autoimmune diseases, astma and atopic dermatitis. An unsolved question is how to define vit D deficiency or the optimal level of 25 hydroxyvitamin D (25OHD). The European Society Pediatric Gastroenterology and Nutrition and the European Society Pediatric Endocrinology defines a level of > 50 nnmol/l as

sufficient. Vit D is produced in the skin and absorbed from certain foods. It is presently unknown how much vit D is produced in the skin of infants, if this amount is sufficient to reach a level of 25OHD above 50 nmol/L. The production of vit D in the skin is higher in summer compared to winter. Studies in 6-8 year old children found that up to 50% of these children in the Netherlands have 25OHD levels < 50 nmol/l in wintertime. The difference in vit D production between summer and winter might be very important in Murmansk, a city in the far North of Russia. No study so far evaluated if the recommended dose of vit D, 400-600 IU is sufficient for infants in winter in Murmansk or also needed in summer time. The role of calcium intake, levels of plasma PTH, 25OHD and fibroblast-growth factor 23 (FGF23), an important phosphate regulating hormone, will be evaluated in relation to the severity of rickets, defined by the increase of alkaline phosphatase.

Study objective

Objective: To obtain data to be used for designing a larger scale study on the incidence of 25OHD levels below the recommended level of 50 nmol/l in children in Murmansk, Russia and Groningen, the Netherlands.

Study design

Study design: Observational study with invasive methods (blood taking). Serum calcium, phosphate, alkaline phosphatase, and plasma 25OHD, PTH and FGF23 will be measured in children 1-4, 5-8 and 9-12 years in both Groningen and Murmansk. Blood will be taken in July/August and January/February

Study burden and risks

De risico's en belasting van het onderzoek zijn minimaal. Op basis van gegevens uit deze studie kan een veel gerichtere studio opgezet worden naar de eventuele noodzaak van suppletie van vit D bij kinderen op verschillende leeftijden, in de winter en/of de zomer en in Murmansk en Groningen. Dit is van groot belang voor grote groepen kinderen.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

healthy children where blood is taken for medical reasons

Exclusion criteria

disorders of calcium and bone metabolism, non caucasian

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL70498.042.19