# PREP-cariesrisk-study;Prevalence of vitamin D deficiency, enamel composition and associations with dental demineralisations in high caries-risk children treated under ambulatory anesthesia

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The aim of this study is to assess the vitamin D (25(OH)D3) level in 3 and 4 years old high caries risk children. These children are referred to Dutch secondary dental care clinics for restorative treatment. Subject will be selected from children...

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

# **Summary**

### ID

NL-OMON45730

**Source** ToetsingOnline

Brief title PREP-cariesrisk-study

# Condition

• Other condition

**Synonym** caries, dental decay

### **Health condition**

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caries

**Research involving** 

Human

### **Sponsors and support**

**Primary sponsor:** Meander Medisch Centrum **Source(s) of monetary or material Support:** kindermondzorgpraktijk Snoet,kindertandartspraktijk Kindertand,Kindertandartspraktijken staan garant voor de kosten;waarnaast een subsidieaanvraag bij de Nederlandse Vereniging voor Kindertandheelkunde is gedaan.

### Intervention

Keyword: caries, caries risk, children, vitamin D

### **Outcome measures**

#### **Primary outcome**

Primary study parameters/outcome of the study: primarily the study will focus

on the caries score and hypomineralisations. The caries status is done with the

ICDAS score, a Likert type score with clinical endpoints (Healthy: ICDAS 0;

Initial lesion: ICDAS 1 or2; Medium lesion: ICDAS 3 OR 4; Serious lesion: ICDAS

5 or 6). Also the total number of decayed teeth is assessed using the dmf-t

score. Using ICDAS a validated oral health outcome is assessed. Separately

enamel disturbances are scored on a scoring list (Elfrink et. al. 2010) to

support further research on hypomineralisations in deciduous teeth (Ghanim et

al 2015).

#### Secondary outcome

Secondary study parameters/outcome of the study (if applicable): Mainly health related variables related to environmental variables and vitamin D. Questionnaires will provide information on date of birth, sex, parental education, housing and schooltype just as data on sun exposure, vitamin D

intake (in foods and supplementation), food pattern. Correlations between all

possible caries and health variables will be calculated whenever possible.

# **Study description**

#### **Background summary**

In 2009 the Dutch research institute TNO stressed the importance of a large study on the vitamin D status of young children since this might be a possibly underestimated problem. Recent dental literature came up with clear indications that a child\*s vitamin D status can be a determinant in the child\*s caries risk. When and if this might indicate that vitamin D suppletion next to oral hygiene instructions and supervising a toothfriendly diet might be beneficial for improving a child\*s oral health, this can be an important point of attention in the near future.

#### **Study objective**

The aim of this study is to assess the vitamin D (25(OH)D3) level in 3 and 4 years old high caries risk children. These children are referred to Dutch secondary dental care clinics for restorative treatment. Subject will be selected from children that are treated in full anesthesia (convenience sample). The results of this study will improve the knowledge on the relation between the severity of dental decal and the prevalence of vitamin D deficiency in children. Health support and information on dental decay can be combined with general health information. Moreover correlations can be studied on the relation between vitamin D status on one hand and sun exposure, skin pigmentation, feeding patterns and vitamin D suppletion on the other. This study can focus on the vitamin D status of high caries risk toddlers and can be the starting point of a new focus on preventive dental health education.

### Study design

This study has a crossectional observational design. It is based on health questionnaires, filled out by the parents and a detailed caries assessment by the operating dentist. Also, during the full anesthesia treatment (see aim) a few drops of blood will be drawn with a fingerstick to assess the vitamin D blood level. Measurements will take place in the period march/april and september/oktober 2017. In this period approx. 320 children will be treated in full anesthesia in the related secondary dental care clinics.

#### Study burden and risks

None other than the treatment routine.

# Contacts

#### Public

Meander Medisch Centrum

Maatweg 3 Amersfoort 3813TZ NL Scientific Meander Medisch Centrum

Maatweg 3 Amersfoort 3813TZ NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Children (2-11 years)

# **Inclusion criteria**

Age: children of 3 and 4 years Sample from patients of the participating secondary dental care practices See protocol page 18.

### **Exclusion criteria**

Malabsorption because of celiac disease, cystic fibrosis or inflammatory bowel diseases Chronic liver or renal diseases Use of medication influencing the vitamin D metabolism such as oral glucocorticosteroids (prenison tablets) and anticonvulsants Contra-indication for blood sampling such as known coagulation disorder Reduced immune status, HIV/AIDS/TBC

# 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:	Recruitment stopped
Start date (anticipated):	30-08-2017
Enrollment:	250
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	07-08-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

# **Study registrations**

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# 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 CCMO **ID** NL59723.100.16