# Influence of vitamin K status on bone metabolism and vascular calcifications in children with renal failure on dialysis

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To determine the vitamin K status in children with chronic renal failure (peritoneal dialysis patients, hemodialysis patients) and evaluate whether a correlation between bone and vascular parameters and vitamin K status exists. If vitamin K status...

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

## Summary

#### ID

NL-OMON32108

**Source** ToetsingOnline

**Brief title** Vitamin K status in children on dialysis

### Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Renal disorders (excl nephropathies)

**Synonym** chronic renal failure; children on dialysis

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Ministerie van OC&W,bedrijven (Ferring en

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Genzyme); die een onderzoeksbeurs beschikbaar gesteld hebben, Ferring, Genzyme

#### Intervention

Keyword: bone metabolism, dialysis, osteocalcin, vitamin K

#### **Outcome measures**

#### **Primary outcome**

Identification of impaired vitamin K status in children on dialysis and

identification of possible correlation with parameters of bone metabolism and

parameters of cardiovascular status.

#### Secondary outcome

correlation of vitamin K status with dietary intake en with loss of vitamin K

in dialysis fluid

# **Study description**

#### **Background summary**

Vitamin K is besides a co-factor in coagulation proteins also a necessary co-factor for osteocalcin and matrix Gla protein (MGP). These vitamin K dependent proteins play an important role in regulation of bone formation and inhibition of vascular calcifications respectively. Renal bone disease and cardiovascular disease are both significant problems for patients with chronic kidney disease. Current dietary requirements of vitamin K are based on the maintenance of normal concentrations of prothrombin, not of osteocalcin and MGP.

Osteocalcin, also named bone Gla protein (BGP), is a 49 amino-acid protein with 3 gamma-carboxyglutamate (Gla) residues. Vitamin K is a necessary co-factor to effectively carboxylate osteocalcin. Increase of vitamin K intake results in markedly higher carboxylation rate of osteocalcin. Beneficial effects of vitamin K on prevention of bone fractures in adults were found in several studies. In healthy children subclinical vitamin K deficiency has recently been described and a better vitamin K status was found to be associated with an increased bone mineral content . In adult patients on haemodialysis suboptimal vitamin K status has been found as well. MGP is a 84 amino acid Gla protein, containing 5 Gla residues. It is found in bone and cartilage, but is also expressed by chondrocytes and vascular smooth muscle cells . Arterial calcification results from the imbalance between factors favouring calcium deposition and inhibitory factors of deposition of calcium. Several studies indicate MGP plays a major role in the inhibition of vascular calcification.

#### **Study objective**

To determine the vitamin K status in children with chronic renal failure (peritoneal dialysis patients, hemodialysis patients) and evaluate whether a correlation between bone and vascular parameters and vitamin K status exists. If vitamin K status is suboptimal, in a later stage oral vitamin K supplementation can be given to improve vitamin K status.

#### Study design

Children on dialysis will be recruited from paediatric nephrology departments in two University hospitals in the Netherlands (Nijmegen and Utrecht). These patients are seen frequently at the out-patient clinic. For follow-up regular visits will be used. In total 20-30 patients will be recruited.

At baseline blood sampling will be performed from all patients (during regular vena puncture) for analysis of vitamin K status blood parameters of bone metabolism, radiologic parameters of bone metabolism and blood parameters of increased cardiovascular risk.

Patients on peritoneal dialysis will be asked to bring a sample of used dialysis fluid.

during 1 week patients will be asked to keep a diary of their dietary intake

#### Study burden and risks

no extra risks Possible benefit: extreme vitamin K deficiency (<3SD of normal value) that might be detected will be treated

# Contacts

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### **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Adolescents (12-15 years) Adolescents (16-17 years) Children (2-11 years)

### **Inclusion criteria**

Patients on peritoneal dialysis and hemodialysis from 1-16 years old

### **Exclusion criteria**

metabolic diseases, known soy allergy, chronic inflammatory bowel disease, use of oral anticoagulants

# Study design

### Design

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

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### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	30
Туре:	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 CCMO ID NL22748.091.08