# : Long-term follow up of growth and bone mineralization of former preterm infants

Published: 27-02-2014 Last updated: 23-04-2024

To determine whether increased calcium and phosphate intake (2005 group) resulted in improved Bone Mineral Content (BMC) and Bone Mineral Density (BMD) compared to the group with less calcium and phosphate intake (2004 group) at the age of 8-10...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

# Summary

### ID

NL-OMON37966

**Source** ToetsingOnline

Brief title FoBoMin

# Condition

- Other condition
- Neonatal and perinatal conditions

#### Synonym

bone mineralisation and length

#### Health condition

follow up van botmineralisatie en groei

#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Ministerie van OC&W,Friso, "unrestricted grant" voor vakgroep kindergeneeskunde Radboud UMC

#### Intervention

Keyword: bone-mineralisation, calcium and phosphate, follow-up, length

#### **Outcome measures**

#### **Primary outcome**

BMC and BMD measured by DEXA at age 8-10 years

#### Secondary outcome

Secondary objective of the study: To determine whether increased postnatal

calcium and phosphate intake (group 2005) compared to lower postnatal calcium

and phosphate intake (group 2004) at the age of 8-10 years results in:

- improved BTT (bone transit time = speed of sound) with quantitative

ultrasound

- improved length, weight, head circumference

# **Study description**

#### **Background summary**

The survival of preterm infants has improved in recent years, but former preterm infants have a reduced length and bone density in later life compared to peers born at term.

As a fetus accrues two-thirds of its total calcium during the last trimester, infants who are born before that time are deprived of this mineral accumulation. After birth it is difficult to maintain a comparable intake of minerals, because of several factors, such as low mineral reserves, increased requirements, medication and increased rate of bone resorption. Adequate early nutrition is important for adequate intake of minerals, particularly calcium and phosphate. The inadequate provision of nutrients after birth and the increased bone resorption probably lead to the development of metabolic bone disease of prematurity.

In 2005 the composition of the standard parenteral nutrition for preterm infants used at the department of neonatology of the Radboud University Medical Centre (RUMC) was changed, according to international recommendations at that time, to improve postnatal growth and development of very low birth weight infants. Besides an improved protein and energy intake, the new parenteral solution provided a significant increased amount of calcium and phosphate.

As a quality control, we performed a retrospective cohort study of data of patients admitted to the NICU on the first day of life (cmo-nr 2009/323). The data of two cohorts were compared. The first cohort contained infants admitted during 2004, receiving the old standard composition of parenteral nutrition, while the second cohort (2005) received the new composition of parenteral nutrition. Nutritional intake, growth and laboratory results were registered according to the standard procedures of the department daily during the first two weeks, weekly until week 5, at term age and during standard follow up at age of two and five years.

Analysis of these data showed that the children born in 2005 at the age of 2 years tended to demonstrate a better catch-up growth in length compared to the children born in 2004. It is not known whether this improved length has sustained until school age and if the bone density has improved significantly. We therefore designed this study to evaluate growth and bone mineralization of the former cohorts.

We hypothesize that the former preterm infants, born in 2005 with high calcium and phosphate intake, nowadays at the age of 8-10 years have an improved bone mineralization and length compared to the preterm infants, born in 2004 with less calcium and phosphate intake (2004 group).

To determine bone mineralization we will perform a Dual-energy X-ray absorptiometry (DEXA) scan and quantitative ultrasound (QUS).

## Study objective

To determine whether increased calcium and phosphate intake (2005 group) resulted in improved Bone Mineral Content (BMC) and Bone Mineral Density (BMD) compared to the group with less calcium and phosphate intake (2004 group) at the age of 8-10 years, determined by DEXA scan.

Secondary objective of the study: To determine whether increased postnatal calcium and phosphate intake (group 2005) compared to lower postnatal calcium and phosphate intake (group 2004) at the age of 8-10 years results in:

- improved BTT (bone transit time = speed of sound) with quantitative ultrasound

- improved length, weight, head circumference

#### Study design

Observational study

#### Study burden and risks

Parameters used as primary endpoint (DEXA-scan, quantitative ultrasound (tibial speed of sound) are not invasive and not painful. The radiation exposure of a DEXA scan can be considered as a very low dose. This method is seen as golden standard for determination of bone mineral content in children. The quantitative ultrasound, measuring the speed of sound is a quick, simple non-invasive procedure that can be used to evaluate skeletal development.

# Contacts

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# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Children (2-11 years)

## **Inclusion criteria**

Informed consent

A participant of our previous study (birth at gestational age below 34 weeks, admission to the NICU of the Radboud UMC on the first day of life, expected duration of parenteral nutrition more than 5 days)

## **Exclusion criteria**

Not full filling inclusion criteria

At our previous study asphyxia, congenital malformation, renal and hepatic insufficiency at birth were exclusion criteria.

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

## Recruitment

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NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	110
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	27-02-2014

Application type:
Review commission:

# **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
 NL47308.091.13