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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28045

Source
NTR

Brief title
FoBoMin

Health condition

FoBoMin
preterm infants
bone mineralization
length

Sponsors and support

Primary sponsor: Radboud University Medical Centre
Source(s) of monetary or material Support: Friso: unrestricted grant

Intervention

Outcome measures

Primary outcome

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 outcome

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

- improved BTT (bone-transit time= speed of sound (m/sec)) determined with QUS.

- improved length, weight, head circumference

Study description

Study objective

Preterm infants have a reduced length and bone density in later life compared to peers born at term.
In our study we want to determine if preterm infants with different intake of calcium and phosphate in the neonatal period, have a difference in bone mineralization and length at the age of 8-10 years.

We hypothesize that the former preterm infants, with higher intake of calcium and phosphate have an improved bone mineralization and length compared to the preterm infants with less intake of calcium and phosphate.

Study design

just one outpatient visit

Intervention

- Questionnaire

- Anthropometric measurements

- Quantitative ultrasound

- DEXA-scan

Contacts

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Eligibility criteria

Inclusion criteria

The children who were included in a former cohort study were born during the year 2004 (68 children with the old composition of parenteral feeding) and 2005 (79 children with the new composition of parenteral feeding). They had at birth a gestational aged below 34 weeks, were admitted to our NICU of the first day of life and had an expected duration of parenteral nutrition of more than five days.

Of these former cohorts 55 respectively 60 children were seen at the follow-up at two years and these children we have invited for the current FoBoMin study.

Exclusion criteria

- Asphyxia

- Congenital malformation

- Renal or hepatic insufficiency at birth

- No follow up at 2 years of age

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2014
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-10-2014
Application type:	First submission

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
NTR-new	NL4413
NTR-old	NTR4842
Other	METC : 2013/594

Study results