

# Influence of corticosteroids and prematurity on bone density in preterm neonates

Published: 23-04-2007

Last updated: 08-05-2024

To prove that 1 corticosteroids administration is the main factor in diminished bone density of preterm neonates, 2 dexamethasone has more influence than hydrocortisone and 3 children with abberant ricketsscreening have a transient diminished bone...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31000

### Source

ToetsingOnline

### Brief title

Corticosteroids and bone density

### Condition

- Neonatal and perinatal conditions

### Synonym

osteoporosis, rickets

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** Geen geldstroom

## Intervention

**Keyword:** bone density, corticosteroids, neonate, preterm

## Outcome measures

### Primary outcome

Primary outcome of the study is a significant diminished SOS in children who have used corticosteroids as to children who don't have used corticosteroids.

### Secondary outcome

Secondary outcome of the study is a wider influence of dexamethasone on bone density as hydrocortisone.

## Study description

### Background summary

Corticosteroids are frequently used in NICU's to extubate ventilated children who are difficult to wean. Dexamethasone has different (long term) effects on bloodpressure, glucose metabolism, growth and braindevelopment. It also seems to have an effect on bone formation. A previous study investigating the influence of antenatal corticoids on calcium metabolism and the correlation between biochemical parameters in blood and urine and bone density, as measured by speed of sound (SOS), showed a temporary diminished bone density in preterm infants. Hydrocortisone might have less side effects than dexamethasone. There are other factors (intrauterine growth retardation, chronic lung disease and long term hospitalization) that may influence bone development. Comparison of preterm neonates with and without the use of corticoids, with aberrant ricketscreening and healthy preterm neonates would give more insight in the cause of temporary diminished bone density.

### Study objective

To prove that 1 corticosteroids administration is the main factor in diminished bone density of preterm neonates, 2 dexamethasone has more influence than hydrocortisone and 3 children with aberrant ricketscreening have a transient diminished bone density as compared to the normal premature population.

## Study design

Prospective cohort study

## Study burden and risks

SOS measurements by Sunlight Omnisense bone sonometer, is a non-invasive method without radiation. An ultrasound wave is transmitted axial through the bone and read by a probe. The attenuation (in dB/MHz) and the speed (SOS, in m/s) is measured.

Measurements of SOS at the midpoint between the apex of the medial maleolus and the distal patellar apex as a measure for bone density at the day of birth and after 1, 3, 6 and 9 weeks. If corticosteroids are used measurements before the first and after the last gift will be performed as well.

## Contacts

### Public

Isala Klinieken

Dr. van Heesweg 2  
8025 AB Zwolle  
Nederland

### Scientific

Isala Klinieken

Dr. van Heesweg 2  
8025 AB Zwolle  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

3 - Influence of corticosteroids and prematurity on bone density in preterm neonates 14-05-2025

## Inclusion criteria

Infants born with a gestational age of 26-34 weeks.

## Exclusion criteria

Multiple congenital anomalies.

## Study design

### Design

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

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-04-2007
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-04-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

## 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	NL17000.075.07