Intake and growth in late preterms

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Primary Objective: To prospectively obtain the (parenteral/enteral) intake of protein, fat, carbohydrates and calories in moderately preterm infants (32-36 weeks) and obtain prospectively growth data in the first 2 years of life. Secondary Objective...

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

Summary

ID

NL-OMON44660

Source
ToetsingOnline

Brief title
Intake and growth in late preterms

Condition

- Other condition

Synonym
nutritional management and preterms

Health condition

neonatologie, groei, voeding en ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Het onderzoek wordt grotendeels gefinancieerd vanuit het Medisch Centrum Alkmaar (personele kosten).Tevens gebruiken we

wetenschapsgeld dat verkregen van Nutricia BV ivm een voedingsleveringscontract voor de afdeling dat is gelabeld voor wetenschappelijke activiteiteten. Hiervan wordt de researchverpleegkundige betaald. Nutricia BV heeft verder geen bemoeienis of inbreng in het onderzoek zelf en is dan ook geen sponsor. ,Nutricia BV

Intervention

Keyword: Body Composition, Developmental Outcome, Nutritional management, Preterms

Outcome measures

Primary outcome

Main study parameter/endpoint:

To prospectively obtain the (parenteral/enteral) intake of protein, fat, carbohydrates and calories in 200 moderately preterm infants (32-36 weeks) and obtain prospectively growth data in the first 2 years of life. The main study parameter is to correlate the intake data with the postnatal growth data at the age of 2 years.

Secondary outcome

Secondary study parameters/endpoints:

The intake and growth data will be compared with a Bayley Scales of Infant development (BSID-III) test at the age of 24 months to determine whether intake or growth in the first 2 years of life is a risk factor for an impaired motor or mental development. Thirdly, a body composition measurement at the age of 2 years will be performed to determine whether intake and growth in the first 2 years of life have an effect on body composition in moderately preterm infants. This could indicate whether these infants will be at risk for long term morbidities like the metabolic syndrome as described in extremely preterm infants. The goal is to obtain the Bayley scores of mental and motor

development and the body composition of 100 moderately preterm infants.

Study description

Background summary

Moderately preterm infants (late preterms, gestational age 32-36 wks) show impaired growth and increased morbidities such as behavioural problems and developmental delays compared to term infants. They have not been routinely followed and it has been thought that they were at a relatively low risk of developing neurological abnormalities. There are no prospective studies performed in these infants to determine whether suboptimal intakes in feeding and impaired growth might play a role in these morbidities.
It might be possible, as shown in extremely preterm infants by Lucas and al. (Lancet 1990) that optimalizing protein and caloric intakes might result in better growth and outcome in these moderately preterm infants. No studies have been performed analyzing prospective protein and caloric intake and growth parameters in the 32-36 weeks preterms. Thereby, no study combined these prospective growth and intake data with a developmental scale at 2 years of age. Combining the intake and growth data with a body composition measurement could also determine whether these moderately preterms are at risk to develop long term morbidities like metabolic syndrome as has been suggested in extremely preterms by Singhal et al. (Lancet 2004). This could lead to new insights and might result in new strategies to decrease morbities in this "relatively forgotten" group of late preterm infants.

Study objective

Primary Objective:
To prospectively obtain the (parenteral/enteral) intake of protein, fat, carbohydrates and calories in moderately preterm infants (32-36 weeks) and obtain prospectively growth data in the first 2 years of life.

Secondary Objective(s):
- To determine whether intake and/or growth in the first 2 years influences motor and/or mental development at the age of 24 months. The intake and growth data will be compared with a Bayley Scales of Infant Development (BSID-III) test at the age of 24 months to determine whether intake or growth in the first 2 years of life is a risk factor for an impaired motor or mental development.

- To determine whether intake and/or growth in the first 2 years of life influences body composition at the age of 2 years. This could indicate whether these infants are at risk for long term morbidities like the metabolic syndrome

as described in extremely preterm infants (<32 weeks).

Study design

The study will be an open, non-therapeutic exploratory study. The intake of fat, protein, carbohydrates and calories will be collected in all infants born 32-36 weeks or transferred to the neonatology ward of the Medical Center Alkmaar (MCA). Subjects will be weighted weekly at the Neonatology Ward of the MCA, their head circumference and length will me measured weekly until they are discharged. The data of the protein, fat, carbohydrates and calories intake will be daily observed (e.g. actual intakes instead of prescribed intakes) by the research nurse by using the day lists of the children filled in by the nurses. The growth will be weekly determined in the Growth Round that is held as standard care every Wednesday morning. After discharge, the infant will be followed at the Outpatient Ward at the age of 6 weeks, 3 months, 6 months, 1 year and 2 years as standard care. At these moments the intakes will be collected by using a diet list and the growth will be determined by the use of the weight, length and head circumference that is measured by the research nurse or the doctor. At 2 years, the growth data are collected by measuring the weight, length and head circumference as standard care. In the infants of which parents consented for the study procedures, a BSID III will be performed by a specialist physiologist of the MCA together with a specialised children*s physiotherapist of the MCA at the age of 2 years. Secondly, a body composition measurement will be performed at the age of 2 years by using the double labelled water techniques. Total body composition (TBW) can be measured by using a single dose of deuterium (D2O). The use of deuterium dilution is save and non-invasive. Stable isotopes are non-radioactive, not detrimental and are already naturally present in the human body in small amounts. An small amount (3 ml per kilogram body weight) of 2H2O will be administered. Saliva samples can be easily collected by swabbing a dry cotton rod in the child*s mouth for 2-5 minutes. Both methods are non-painful. No extra blood samples are needed.

Study burden and risks

The study is a non-therapeutic, exploratory cohort study. It concerns preterm infants born between 32 and 36 weeks of gestation that are followed untill the age of 2 years. They are minors and thereby incapacitated subjects. The study will be non-therapeutic in which the infants have no benefits. It will not be an intervention study which makes the risks for SAE*s neglectable. Regarding the CCMO guidelines in minors the risk must be neglectable and the objections must be minimal. In our study, the use of the BSID III will take 2.5 hours of time. It is a developmental tool that is performed in all preterm infants born < 32 weeks as routine assessment in the Netherlands at the age of 2 years. In these children it is experienced as minimally objective .
The use of deuterium dilution is save and non-invasive. Stable isotopes are

non-radioactive, not detrimental and are already naturally present in the human body in small amounts. An small amount (3 ml per kilogram body weight) of 2H2O will be administered. Saliva samples can be easily collected by swabbing a dry cotton rod in the child*s mouth for 2-5 minutes. In previous studies that are performed in children using deuterium dilution the procedure is minimally objective and safe.

Benefits and group relatedness:
In these moderately preterm infants a benefit could be that by standardising the feeding regimen at the ward and performing the weekly Growth round, the growth and intake in these late preterms will improve. In different studies in extremely (<32 wks) preterm infants it has been shown that standardisation of feeding protocol and weekly feeding rounds can result in less growth retardation and might influence later outcome (ref toevoegen). If we can show that by monitoring intake and growth as standard care as is performed in our Neonatology department can result in a normal neurodevelopment and not result in abnormal body composition, all moderately preterm infants in the world can benefit in the future.
No study has been performed analyzing prospective protein and caloric intake and growth parameters in the 32-36 weeks preterms. Thereby, no study combined these prospective growth and intake data with a developmental scale at 2 years of age. Combining the intake and growth data with a body composition measurement could also determine whether these moderately preterms are at risk to develop long term morbidities like metabolic syndrome as has been suggested in extremely preterms (32). This could lead to new insights and might result in new strategies to decrease morbities in this "relatively forgotten" group of late preterm infants.
Concluding, the risks are neglectable, the burden is minimal and it this study could result in answers or new research questions why this late preterm group shows morbidities in growth and development in retrospective studies. This implicates that the research-question is group-related and can only be performed in this group of infants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- born between 32 and 35 6/7 weeks of gestational age
- will not be transferred to an other hospital before discharge
- will visit the Outpatient Clinic of the MCA after discharge

Exclusion criteria

- congenital abnormalities of the gastro-intestinal tract
- cardiac abnormalities
- metabolic or chromosomal/syndromal diseases
- infants that develop necrotising enterocolitis stage IIb or III (NEC)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26379
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50800.094.14
OMON	NL-OMON26379