Intake and growth in late preterms

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26379

Source
Nationaal Trial Register

Brief title
moderately late preterms

Health condition

late preterms
growth
intake
developmental outcome
body composition

Sponsors and support

Primary sponsor: Noordwest ziekenhuisgroep
Source(s) of monetary or material Support: Nutricia Nederland B.V.

Intervention

Outcome measures

Primary outcome

1.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.

2. What is the growth pattern in these late preterms in the first 2 years of life?

Secondary outcome

3. What is the body composition and the developmental outcome of late preterms at the age of 2 years?

4.1s there a relationship between 1;the intake of protein, fat and carbohydrates and 2; growth?

5. Is there a relation betvveen 1; the intake of protein, fat and carbohydrates and 3, the body composition and developmental outcome?

Study description

Background summary

Moderately preterm infants (gestational age 32-36 weeks) 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.

The first objective is to prospectively determine the intake of protein, fat, carbohydrates and calories from birth to the age of 2 years and correlate them with the postnatal growth until the age of 2 years. The second objective is to determine the motor and mental development in these infants by correlating the intake and growth to a Bayley Scales of Infant development (BSID-III) which is used to determine developmental delays in extremely preterm infants. The third objective is to determine whether the intake and growth in the first 2 years of life influences the body composition.

Study objective

Moderately preterm infants (gestational age 32-36 weeks) 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 wheter suboptimal intakes in feeding and/or impaired growth play a role in these morbidities.

Study design

The study will be an open, non-therapeutic exploratory study. The intake of fat, protein and

calories win be collected in all infants born 32-36 weeks at or transferred to the neonatology ward of the Northwest Hospital Group in Alkmaar . The data of actual intake will be collected daily during the stay at the Neonatology ward of the Northwest Hospital Group in Alkmaar and the growth data will be collected during the weekly feeding round that is performed at the Neonatology ward. When infants are discharged, they will be followed at the Outpatient ward of the Northwest Hospital Group in Alkmaar at age term, 6 weeks corercted age, 3 months, 6 months, 1 year and 2 years corrected age. The data will be anonymously imported in a data base.

Intervention

The study will be an open, non-therapeutic exploratory study. The intake of fat, protein and calories will be collected in all infants born 32-36 weeks born or transferred to the neonatology ward of the Northwest Hospital Group in Alkmaar that are being followed at the Northwest Hospital Group Outpatient Clinic in Alkmaar. Prospective data on intake and growth will be collected as routine assessment until the age of 2 years. At the age of 2 years, a developmental test (BSID III) and a body composition measurement by using stable isotopes (single labeled water method) will be performed in the subjects whom parents consented.

Contacts

Public
Noordwest ziekenhuisgroep - Neonatologie/kinderpoli, 119

F.
Maingay-de Groof

Wilhelminalaan 12

1815 JD

Tel: 003172-5482950
Scientific
Noordwest ziekenhuisgroep - Neonatologie/kinderpoli, 119

F.
Maingay-de Groof

Wilhelminalaan 12

1815 JD

Tel: 003172-5482950

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following 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 Northwest Hospital Group in Alkmaar after discharge

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- congenital abnormalities of the gastro-intestinal tract

- cardiac abnormalities

- metabolic or chromosomal/syndromal diseases

- infants that develop necrotising enterocolitis stage IIb or III (NEC)

- infants with chronical diseases that influence growth: e.g. coeliac disease, hypothyroidism, growth hormone deficiency, malabsorption, cow milk allergy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-11-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44660
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5429
NTR-old	NTR5563
CCMO	NL50800.094.14
OMON	NL-OMON44660

Study results