The effect of nutrition on growth, body composition and bone mineralization of late preterm infants.

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Late preterm infants fed an isocaloric, protein- en mineral-enriched (‘postdischarge’) formula (PDF) from term age until 6 months corrected age will be equal in weight, length and head circumference compared to infants fed standard term formula at 6...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28261

Bron
Nationaal Trial Register

Verkorte titel
LEGO

Aandoening

English: late preterms, nutrition, growth, body composition. Dutch: laat-prematuren, voeding, groei, lichaamssamenstelling

Ondersteuning

Primaire sponsor: VU University Medical Center, Amsterdam
Overige ondersteuning: Investigator initiated research.
Sponsor = initiator = VU University Medical Center, H.N. Lafeber, MD, PhD, professor of Neonatology.
Unrestricted research grant: Hero Benelux, Breda, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Growth (weight, length, head circumference);
- Body composition (fat mass, lean mass)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Preterm infants are at risk long term for adverse (metabolic) effects1, which may be explained by the “fetal origins hypothesis” and the “catch up growth hypothesis”. 2-4 Prematurity and excessive growth during early childhood are risk factors for the development of obesity, diabetes, hypertension and cardiovascular disease in later life. 3,5-10 Research mostly focuses on early preterm born children (<32 weeks gestational age). Limited research has been performed to look into the effects on late preterms (gestational age between 32 and 36 weeks) so far. Lapillonne et al. state that late preterms require special attention since they have unique and often unrecognized medical vulnerabilities and nutritional needs. 11,12 We think this assumption has yet to be supported by evidence so the specific needs can be further explored and specified. Research among preterms in general, aims at an optimal balance between sufficient growth on one side and risks associated with excessive (catch-up) growth and fat accumulation on the other side. 6,13,14 We hypothesize that an isocaloric, protein- and nutrient-enriched (‘postdischarge’) formula fed to late preterm infants will promote both growth and a favorable body composition and thereby diminish the previously mentioned health risks. For SGA born children we expect this effect to be even more pronounced since both term and preterm SGA infants seem to benefit from nutrient enriched formula. 15,16 Male infants seem to profit most from PDF feeding. 17 With stratification at randomisation for both gender and being SGA or not, we hope to give more insight in those differences.

Objective: The main objective is to compare growth and body composition of late preterm infants at 6 months corrected age, fed either an isocaloric, protein- and mineral-enriched (‘postdischarge’) formula (PDF) or standard term formula (TF) between term age and 6 months corrected age. The secondary objective is to compare cardio-metabolic risk factors, bone mineral content and endocrine parameters. Furthermore, we will compare the formula fed infants to the infants fed human milk.

Study design: Double-blinded randomized controlled multicenter trial (VUmc and affiliated clinics).
Study population: 200 late preterm infants with a gestational age at birth between 32 0/7 and 35 6/7 weeks and born appropriate for gestational age (birth weight between 10th and 90th percentile; p10-p90), small for gestational age (birth weight p90) will be included for randomisation. In addition a maximum of 100 human milk fed infants will be included as a

control group.

Intervention: All infants will be fed PDF from birth to term age (unless they receive human milk). At term age, formula fed infants are randomized to PDF or TF and are fed this diet until six months corrected age. Stratification for gender and birth weight (p10) will be performed.

Main study parameters: Weight, length, head circumference, body composition and bone mineral content.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In the first week after birth a blood sample (3.0ml) will be taken, either together with a routine clinical venepuncture or with placement of an IV-cannula for parenteral nutrition. Subjects will visit the outpatient clinic of the VU University medical center twice (around term age and corrected age 6 months). At both visits anthropometry, measurement of body composition in the PEA POD and a whole body DEXA-scan will be performed and a blood sample (4.2ml) will be taken. One home visit around age three months to deliver formula and collect growth data. During the period from discharge until 6 months, parents will keep a diary of the nutritional intake of their child.

Doel van het onderzoek

Late preterm infants fed an isocaloric, protein- en mineral-enriched ('postdischarge') formula (PDF) from term age until 6 months corrected age will be equal in weight, length and head circumference compared to infants fed standard term formula at 6 months corrected age. We expect the group fed PDF to have a healthier body composition (more lean mass, less fat mass) and a similar or improved bone mineral content at 6 months corrected age.

Onderzoeksopzet

- within 7 days after birth

- around term age (40 weeks gestational age)

- 6 months corrected age

- ongoing: dietary diary + anthropometric measurements performed in between study visits

Onderzoeksproduct en/of interventie

All participants will be fed human milk and/or the isocaloric, protein- and nutrient-enriched formula ('Hero baby Prematuur 1') from birth until term age (40 weeks gestational age). We decided to use one type of formula in this period to create a relatively comparable reference point at term age, before start of the intervention. The choice for the enriched formula is based on the assumption that late preterms like other preterms are in need of extra protein for both growth and neurodevelopment and extra minerals for bone mineralization. Whether this is still desirable after term age will be investigated within this study.

For formula fed infants our intervention consists of randomisation at term age to two different formula-groups, both used in standard care for (preterm) infants in the Netherlands. From term age until 6 months corrected age two formulas will be used;

- Standard term formula (TF / ‘Hero baby Standaard 1’)

- Isocaloric, protein- and mineral-enriched (‘postdischarge’) formula (PDF / ‘Hero baby Prematuur 1’)

The third group will consist of infants that receive (mostly) human milk (control group);

If daily intake consists of <75% human milk before term age, subjects will be randomized to one of the two formula groups at term age. Until term age, they will be fed PDF in addition.
o Subjects that receive human milk until term age or beyond will in case of cessation (<75% of daily intake consists of human milk) be allocated to the standard term formula group in order to avoid heterogeneity of groups.

o Breast milk fortifier will be advised until term age (40 weeks gestational age).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- birth between 32 0/7 and 35 6/7 weeks gestation

- inclusion will only take place when written informed consent from both parents is obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- gastro-intestinal surgery and disease known to influence growth (i.e. cystic fibrosis and severe gastro-oesophageal reflux);

- known presence of growth hormone, IGF-1 or other pituitary hormone deficiencies;

- concurrent therapies with substances known or suspected to be associated with alteration of growth (i.e. oral steroids);

- cardiac, renal, pulmonary and liver disease;

- chromosomal and/or genetic syndromes;

- known skeletal disease;

- severe illness.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55631
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4979
NTR-old	NTR5117
CCMO	NL47957.029.14
OMON	NL-OMON55631

Resultaten