Effect of Peak Baby Preterm on growth and nutritional status of Nigerian late preterm infants.

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

Samenvatting

ID

NL-OMON21985

Bron
NTR

Aandoening

Growth, nutritional status, apparently healthy late preterm infants, Nigeria, DHA, Iron, Vitamin A, Vitamin D

Ondersteuning

Primaire sponsor: Department of Pediatrics, College of Medicine University of Ibadan, Ibadan, Nigeria
Overige ondersteuning: FrieslandCampina, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the effect on growth of a newly developed preterm formula in apparently

healthy Nigerian preterm born infants with a gestational age of 32-34 weeks, up to a body weight of 3500 g but at least during a period of 8 weeks.
To determine the effect of the formula on blood status parameters of DHA-AA, vitamins D & A, and iron.

Toelichting onderzoek

Doel van het onderzoek

Infants on Peak Baby Premature will have a balanced growth (weight-height) in accordance with what can be considered normal for the target population (based on gestational age) and as shown by the use of specific growth charts and or local intrauterine growth curves, The product will also realize normal concentrations (in accordance with reference values) of DHA, vitamin A, vitamin D and iron in blood or red blood cells. Infants on Peak Premature will at least not increase the number of hospital days as compared to breast milk fed infants.

Onderzoeksopzet

Weekly measurements of growth parameters, blood samples at 14=/- 2 days and 75+/- 2 days for nutritional parameters, tolerance at the start, midway and end of the study.

Onderzoeksproduct en/of interventie

Formula feeding versus breastfeeding

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

apparently healthy, appropriate for gestational age, on full enteral feeding, bottle (at least 50% at inclusion and 100% at age 4 weeks) or breastfed (at least 75% of daily milk intake) dependent on the study groups, being able and willing to drink milk, no medical recognized mental problems.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

>50% human milk at inclusion (for the formula group) or >25% formula consumption (for the breastfed group), congenital malformations or conditions known to affect growth (e.g. severe broncho pulmonary dysplasia, inborn error of metabolism, cardiac or renal disease, necrotizing enterocolitis with substantial gut loss, and grade IV intraventricular hemorrhage), lactose intolerance, familiar history of impaired iron metabolism (haptoglobin Hp2-2, hemochromatosis, sickelcell anemia, thalassemia). Medications that may effect digestion or absorption of food, medications that may affect sleep, blood transfusions, vitamin supplements during the intervention period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-12-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6025
NTR-old	NTR6156
Ander register	FrieslandCampina : 2016-001-GND

Resultaten