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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21985

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Department of Pediatrics, College of Medicine University of Ibadan, Ibadan, Nigeria
Source(s) of monetary or material Support: FrieslandCampina, The Netherlands

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To get insight in the acceptance of the formula and breast milk by these healthy late preterm infants by using a tolerance questionnaire.

To compare the effects on biochemical nutrient status parameters and growth of the preterm formula with those of breastfed infants.

To get insight in the number of hospital days in both groups (formula and breast milk).

Study description

Study objective

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.

Study design

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.

Intervention

Formula feeding versus breastfeeding

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

>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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-12-2016
Application type:	First submission

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
NTR-new	NL6025
NTR-old	NTR6156
Other	FrieslandCampina : 2016-001-GND

Study results