The effect of Friso Premature on growth, sleep characteristics, Nutritional status parameters and inflammatory markers.

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The addition of a whey protein hydrolysate will improve sleep onset and efficiency and will not limit growth in weight, length and head circumference as compared to the control preterm formula at the age of 10 weeks. Because of the alkaline...

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

Samenvatting

ID

NL-OMON25053

Bron
Nationaal Trial Register

Aandoening

Sleep efficiency, growth, nutritional status, inflammatory markers.

Slaap efficientie, groei, voedingskundige status, ontstekings indicatoren.

Ondersteuning

Primaire sponsor: Specialized Hospital for Active Treatment of Children’s Disease, Sofia, Bulgaria
Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Growth;
2. Sleep efficiency;
3. Nutritional status of iron, vitamin D, vitamin A, folic acid, and DHA-AA.

Toelichting onderzoek

Achtergrond van het onderzoek

In 2010 the ESPGHAN released new recommendations with regard to the composition of formulae for preterm infants. This resulted in quite some discussions about the necessity of some changes. For that reasons it was decided to look for the differences in outcome between the current and ESPGHAN aligned composition. Furthermore, the use of protein hydrolysate should show off in a more tolerable product for preterm infants.

Doel van het onderzoek

The addition of a whey protein hydrolysate will improve sleep onset and efficiency and will not limit growth in weight, length and head circumference as compared to the control preterm formula at the age of 10 weeks.

Because of the alkaline composition, nocturnal acidosis will be significantly lower as compared with the current available preterm formula during the course of the study.

Nutritional status of iron, vitamin A, vitamin D, DHA-AA and folic acid will be more close to normal/required as compared to the current formula at the age of 10 weeks.

Inflammatory and oxidation markers will be lower than in case of the current preterm formula during the course of the study.

Onderzoeksopzet

The intervention period will last for 8 weeks and the several parameters will be studied at the start (age 14±2 days), and at the age of 30±2 days, 45±2 days and 75±2 days. Venous blood samples will only be collected at 14±2 days and 75±2 days.

Methods of measurement:

1. Anthropometry: Body weight, height and head circumference according to standard procedures;

2. Tolerance: Based on 3-days diary;

3. Sleep onset and efficieny: By 3 days Actiwatch monitoring and sleep diary;

4. Metabolic acidification: pH measurement of early morning urine, as well as the analysis of potassium and creatinin in urine;

5. Nutritional status parameters: Vitamin D [25(OH)D], vitamin A [serum retinol & retinol binding protein], iron [Hb, serum ferritin, soluble transferrin receptors], folic acid [serum folate] and total homocysteine according to the standard procedures of the Free University medical center, Amsterdam, The Netherlands. Red blood cell fatty acid composition according to the standard procedure of the University Medical Center Groningen, The Netherlands;

6. Inflammatory status: F2 isoprostanes in early morning urine and c-reactive protein, Interleukin-6 and TNF-alpha in plasma, according to standard procedures of the Free University medical center, Amsterdam, The Netherlands.

Onderzoeksproduct en/of interventie

A. Current formulae for preterm infants during the hospital phase (till 3500 g of body weight);

B. Preterm formulae with protein hydrolysate, and increased levels of some vitamins and minerals in accordance with the ESPGHAN guidelines.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Apparently healthy infants, appropriate for gestational age (AGA);

2. Gestational age of 32 up to but not including 35 (ongoing) weeks;

3. Full enteral nutrition;

4. Not younger than 2 or older than 3 weeks of age at inclusion;

5. Bottle fed;

6. Being able and willing to drink milk;

7. No medical recognized mental problems.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Human milk consumption;

2. 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);

3. Lactose intolerance;

4. Familiar history of impaired iron metabolism (haptoglobin Hp2-2, hemochromatosis, sickelcell anemia, thalassemia);

5. Medications that may effect digestion or absorption of food, or affect sleep;

6. Blood transfusions;

7. Vitamin supplements during the intervention period.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-03-2012
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	NL3221

Register	ID
NTR-old	NTR3373
Ander register	FrieslandCampina : Nutr-AS-004-2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A