Study Towards the Effects of Post discharge nutrition on growth and body composition of infants born

Gepubliceerd: 21-07-2005 Laatst bijgewerkt: 18-08-2022

To study the effects of post dicharge nutrition on the growth, body composition, metabolism and neurodevelopment of premature infants . To study the effects of catch-up growth on the body composition, metabolism and neurodevelopment of premature...

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

Samenvatting

ID

NL-OMON26207

Bron
NTR

Verkorte titel
STEP

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Growth and body composition (bone density, fat percentage).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

To study the effects of post dicharge nutrition on the growth, body composition, metabolism and neurodevelopment of premature infants .

To study the effects of catch-up growth on the body composition, metabolism and neurodevelopment of premature infants.

Onderzoeksproduct en/of interventie

Randomization to post discharge or term formula between 0 and 6 months corrected age. Breast milk group as a control group.

All the formula and the breast milk with fortifier are prescribed in a volume of ± 175 ml/kg/day (160-190ml/kg/day).

The infants are seen at the outpatient clinic at 0, 3, 6, 12 and 24 months corrected age. Anthropometry is performed and motorneurodevelopment is tested by a physiotherapist. At 0, 3 and 6 months corrected age a fasting venous blood sample is taken and urine is collected. At 0 and 6 months corrected age the body composition is established with a DEXA scan. Parents keep weekly dairies and telephonic support is offered on a regular bases.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Gestational age <= 32 weeks with a birth weight <= 2000 grams or a birth weight <= 1500 grams and a gestational age <= 34 weeks.
At least one parent or caretaker who speaks Dutch or English.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Conditions that influence the growth like:

1. Severe congenital anomalies;

2. Bronchopulmonary dysplasia defined as an O2 requirement above 25% at 36 weeks gestation, any O2 requirement at 38 weeks gestation or any respiratory support at 40 weeks gestatio';

3. Severe intracerebral haemorrhage or ischaemia diagnosed before inclusion;

4. Gastrointestinal surgery and gastro-intestinal diseases known to influence growth.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2003
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2005
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	NL32
NTR-old	NTR55
Ander register	: N/A
ISRCTN	ISRCTN53695702

Resultaten

Samenvatting resultaten

Publications: Amesz EA, Schaafsma A, Cranendonk A, Lafeber HN. Optimal growth and lower fat mass in preterm infants fed a protein-enriched postdischarge formula. JPGN 2010;50:200-207.

Brief summary: Feeding nutrient-enriched formula without extra energy after term does not change quantity of growth, but does influence type of weight gain and body composition of preterm infants. Infants fed the nutrient-enriched formula had lower fat mass corrected for body size at six months corrected age than infants fed standard formula or human milk. There were no differences in growth or body size between infants fed postdischarge formula, standard formula, and human milk.