Post LaUnch monitoring pretermS.

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Protein Supplement, used for extremely-low-birth-weight (ELBW) infants (< 1000 g) in addition to human milk and/or preterm formula in daily practice, is well tolerated and safe.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24765

Bron
NTR

Verkorte titel
PLUS

Aandoening

Preterm infants with extremely low birth weight (< 1000 g).

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialised Nutrition
Overige ondersteuning: Danone Research - Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Growth (gain in body weight, length and head circumference);
2. Gastrointestinal symptoms;
3. Serious Adverse Events (SAEs).

Toelichting onderzoek

Achtergrond van het onderzoek

ELBW infants can be recruited into the test group of the study when the use of the Protein Supplement is indicated by the treating medical doctor. After informed consent is obtained from the parent(s)/legal guardian(s), ELBW infants follow the standard daily hospital care. Data on growth, tolerance, safety and nutrition is captured as recorded during standard daily practice.
No additional analyses or measurements are performed for the study in the hospital. The study does not intervene with the hospital daily routine.
The control group comes from historical data collected of ELBW infants.

Doel van het onderzoek

Protein Supplement, used for extremely-low-birth-weight (ELBW) infants (< 1000 g) in addition to human milk and/or preterm formula in daily practice, is well tolerated and safe.

Onderzoeksopzet

As this is an observational study no interventions will be done on set time points. Infants will follow routine hospital care.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

PO Box 7005
Sandra Helderman-Swart
Wageningen 6700 CA
The Netherlands
+31 (0)371 467800

Wetenschappelijk

PO Box 7005
Sandra Helderman-Swart
Wageningen 6700 CA

The Netherlands
+31 (0)371 467800

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Birth weight of < 1000 g;

2. Gestational age s 36 weeks;

3. Decision of the treating medical doctor to start using the Protein Supplement (not applicable for control group);

4. Written informed consent by parent(s)/legal guardian(s) (not applicable for control group).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. (Anticipated) transfer to another hospital within 2 weeks after start of full enteral feeding;

2. Major congenital disorders interfering with the protocol requirements as per investigator's clinical judgement;

3. Chromosomal aberrations interfering with the protocol requirements as per investigator's clinical judgement;

4. Systemic metabolic diseases;

5. Participation in any other studies involving investigational or marketed products interfering with the study conduct, as per investigator's clinical judgement.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-03-2013
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3714
NTR-old	NTR3877
Ander register	Danone Research BV : SPC.1.C/B
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
No