Early Nutrition Study.

Gepubliceerd: 05-01-2012 Laatst bijgewerkt: 19-03-2025

We hypothesize that feeding VLBW infants with a diet that is completely based on human milk during the first 10 days of life will result in a decrease in the incidence of serious infections, necrotizing enterocolitis (NEC), and neonatal mortality.

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

Samenvatting

ID

NL-OMON24223

Bron
Nationaal Trial Register

Verkorte titel
ENS (Early Nutrition Study)

Aandoening

Prematurity; donor milk; very low birth weight infant; late onset sepsis; necrotizing enterocolitis; infant formula; breast milk

Ondersteuning

Primaire sponsor: VU Medical Center, Amsterdam, the Netherlands
Overige ondersteuning: Mead Johnson Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of the combined outcome of serious late-onset infections (sepsis/ meningitis and NEC) and/ or death occurring between age 72 hours and 60 days.

1. Early Supplementation study Amendment (applicable in St. Radboud UMC Nijmegen (RUNMC) en VUmc Amsterdam)
- Primary Outcome: bone mineral content (BMC) and body composition measured by DXA

2. Adrenocortical function amendment (applicable in VUmc)
- Primary Outcome: Urinary cortisol metabolites at days 10 and 30.

3. Body Composition amendment (applicable in VUmc and AMC Amsterdam)
- Primary Outcome: Body composition (body fat%, fat-free mass, lean mass, fat mass, fat-free mass index, fat mass index) and growth at 1, 2 and 5 years of age.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Lack of enteral nutrition results in intestinal atrophy potentially causing increased bacterial translocation, thereby making VLBW infants more prone to sepsis. According to current feeding protocols in NICU's, minimal enteral feeding is initiated within 6 hours after birth. After premature delivery the onset of lactation is often delayed and therefore VLBW infants are often being fed with preterm formula during the first few days of life. Feeding VLBW infants with own mother's milk is to be preferred because it reduces the incidence of sepsis and NEC. When own mother's milk is not available during this period, donor milk might be of benefit to these infants when compared to formula. We hypothesize that feeding VLBW infants with a diet that is completely based on human milk during the first 10 days of life will result in a decrease in the incidence of serious infections, necrotizing enterocolitis (NEC), and neonatal mortality.

Objective:

To determine whether (supplemental) human donor milk has beneficial effects (in terms of reduction of infectious episodes and mortality) when compared to (supplemental) preterm formula during the first 10 days of life in VLBW infants.

Study design:

Double blind randomized controlled trial.

Study population:

VLBW infants admitted to one of the participating centers.

Intervention:

If own mother's milk is not available in sufficient amounts, the intervention group (group A) will receive additional donor milk and the control group (group B) will receive additional standard preterm formula. Donor milk and formula therefore serve as 'add-on' therapy to own mother's milk.

Main study parameters/endpoints:

Main endpoint: Combined incidence of serious infections/NEC and death.

Secondary endpoints: Composition of fecal microbiota, time to full enteral feeding, days on TPN, growth rate, bone density. Bayley Scores of Infant Development III (at 2 years of age), growth rate (at 2 years of age).

28-jun-2014: Three amendments were added (MEC approval for all):
1. Early Supplementation study Amendment (applicable in St. Radboud UMC Nijmegen (RUNMC) en VUmc Amsterdam)
- Rationale: Preterm born infants miss out on active fetal mineralization in utero during

2. Adrenocortical function amendment (applicable in VUmc)
- Rationale: There is a male disadvantage in neonatal mortality, and in acute and chronic conditions after very preterm birth, which could be partially counteracted by nutritional strategies. We speculate that variation in the adrenocortical function underlie these sex-specific observations

3. Body Composition amendment (applicable in VUmc and AMC Amsterdam)
- Rationale: It is likely that the pattern of body composition in preterm infants is in part a consequence of the nutrition they receive during the first period of life. From term infants it is known that throughout the first year of life, formula fed infants have lower fat mass compared to breast fed infants with a switch at 12 months of age. It is possible that this trend continues in later life. We hypothesize that feeding VLBW infants with a diet that is completely based on human milk during the first period of life will result in a lower fat percentage in later life.

Doel van het onderzoek

We hypothesize that feeding VLBW infants with a diet that is completely based on human milk during the first 10 days of life will result in a decrease in the incidence of serious

infections, necrotizing enterocolitis (NEC), and neonatal mortality.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Infants in group A will receive banked donor milk in case their own mother's milk falls short. Infants in group B will receive preterm formula currently in use if their own mother's milk falls short. Infants will receive the study diets until they are 10 days of age. After the intervention period infants will receive the standard feeding regimen, that is (if available) milk of the own mother's + breast milk fortifier or otherwise preterm formula.

1. Early Supplementation study Amendment (applicable in St. Radboud UMC Nijmegen (RUNMC) en VUmc Amsterdam)
- Intervention: Infants born at RUNMC are randomized to either participate in the Early the third trimester and are therefore at risk of reduced bone mineral content (BMC), which may lead to disease in later life. Minerals are administered parentally and via breast milk fortifier. However, fear for nephrocalcinosis and feeding intolerance makes clinicians prudent to administer breast milk fortifier from birth onwards, which may lead to osteopenia. It is currently unknown what is the most optimal timing, amount and route to supply minerals to preterm infants.

Nutrition Study (and therefore receive late mineral supplementation) or to receive early (day of life 4-5) mineral supplementation according to the standard feeding protocol at the RUNMC.

2. Adrenocortical function amendment (applicable in VUmc)
- Intervention: original ENS intervention

3. Body Composition amendment (applicable in VUmc and AMC Amsterdam)
- Intervention: original ENS intervention

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Birth weight < 1500 gram;

2. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Child of mother that abused drugs and/or alcohol during pregnancy;

2. Major congenital anomalies or birth defects;

3. Congenital infection, defined as: Early Onset Sepsis or suspected TORCHES infection;

4. Perinatal asphyxia with (umbilical or first neonatal) pH < 7.0;

5. Intake of any cow’s milk based products prior to randomization.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2012
Aantal proefpersonen:	396
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39540
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3077
NTR-old	NTR3225
CCMO	NL37296.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39540

Resultaten

Samenvatting resultaten
n/a