The effect of intermittent bolus nasogastric milk feeding versus semi-continuous milk feeding in preterm infants on TOLerance.

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Premature infants born under 32 weeks tolerate bolus feeding better than semi-continuous nasogastric milk feeding, so that the number of days to reach full enteral feeding are less.

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

Samenvatting

ID

NL-OMON24267

Bron
Nationaal Trial Register

Verkorte titel
The TOL-study

Aandoening

feeding tolerance
premature infants
intermittent feeding
semi-continuous feeding
voedingstolerantie
premature kinderen
intermitterend voeden
semi-continu voeden

Ondersteuning

Primaire sponsor: J.B. van Goudoever, MD, PhD
Erasmus MC - Sophia Children's Hospital

University Medical Center
Department of Pediatrics
Division of Neonatology
Dr. Molewaterplein 60
3015 GJ Rotterdam
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the effect on both feeding regimes on feeding tolerance. Primary objective is days to reach full enteral feedings, defined as ¡Ý 120 mL/kg/d.

Toelichting onderzoek

Achtergrond van het onderzoek

PROTOCOL SYNOPSIS
Title: the effect of intermittent bolus nasogastric milk feeding versus semi-continuous milk feeding in preterm infants on tolerance
Objectives: to assess the effect of intermittent bolus nasogastric milk feeding versus semi-continuous milk feeding in preterm infants on feeding tolerance.
Study design:single centre, randomized, prospective trial.
Subject selection criteria: preterm infants with gestational age ¡Ü 32 weeks, birth weight < 1750 grams, inborn or admitted within 24 hrs after birth.
Planned sample size: 250 infants.
Test groups:
1. intermittent bolus feeding
2. semi-continuous feeding
Main parameters of efficacy: number of days before full enteral nutrition is achieved, feeding tolerance
Main parameters of safety: necrotizing enterocolitis (Bell¡¯s Stage II or more).
Procedures: 250 infants are studied in two separate groups (125 per group). At study entry, the infants are randomly allocated to receive either intermittent bolus nasogastric feeding or semi-continuous nasogastric milk feeding. All infants are given minimal enteral feeding from day 1 as clinical condition permits. From day 2 increasing amounts of enteral nutrition will be given. During the study period, clinical condition, nutritional intake, and feeding tolerance are recorded daily. Anthropometric data will be obtained at day 1, day 7 and once weekly thereafter, until postnatal day 28.
Statistical analysis: ANOVA for repeated measures. Mann-Whitney U test or student¡¯s t-test

depending the distribution of the variable (non-normal/normal distribution of the variables).

Doel van het onderzoek

Premature infants born under 32 weeks tolerate bolus feeding better than semi-continuous nasogastric milk feeding, so that the number of days to reach full enteral feeding are less.

Onderzoeksproduct en/of interventie

Bolus intermittent nasogastric feeding

Contactpersonen

Publiek

Erasmus Medical Center, Sophia Children's Hospital
P.O. Box 2060
J.B. Goudoever, van
Rotterdam 3000 CB
The Netherlands
+31 (0)10 4636363

Wetenschappelijk

Erasmus Medical Center, Sophia Children's Hospital
P.O. Box 2060
J.B. Goudoever, van
Rotterdam 3000 CB
The Netherlands
+31 (0)10 4636363

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Admission to neonatal intensive care unit within 24 hrs after birth;
2. Gestational age under 32 weeks;
3. Birth weight less than 1750 grams.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Simultaneous participation in another trial of which the intervention may influence this trials endpoints;
2. Congenital gastrointestinal obstructions like duodenal atresia, anal atresia, etc.;
3. Any disease entity known to encompass impaired growth other than small gestational age;
4. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-02-2006
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2007
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	NL871
NTR-old	NTR885
Ander register	: N/A
ISRCTN	ISRCTN42413683

Resultaten

Samenvatting resultaten
N/A