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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24267

Source
Nationaal Trial Register

Brief title
The TOL-study

Health condition

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

Sponsors and support

Primary sponsor: J.B. van Goudoever, MD, PhD
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Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Secondary objective is number of feeding interruptions, days on total parenteral nutrition and number of apnea episodes per day;
2. To assess somatic growth in both feeding regimes. To evaluate this variable, the following items will be used: days to regain birth weight, rates of weight gain, knemometry and head circumference;
3. To assess complications in both groups measured as catheter related sepsis and necrotizing enterocolitis.

Study description

Background summary

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).

Study objective

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.

Intervention

Bolus intermittent nasogastric feeding

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2006
Enrollment:	250
Type:	Actual

Ethics review

Positive opinion

Date:	02-02-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL871
NTR-old	NTR885
Other	: N/A
ISRCTN	ISRCTN42413683

Study results

Summary results
N/A