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

Published: 30-11-2006
Last updated: 09-05-2024

To asses the effect of intermittent bolus nasogastric milk feeding versus semi-continuous milk feeding in preterm infants

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON29985

Source
ToetsingOnline

Brief title
The TOL-study

Condition

- Gastrointestinal motility and defaecation conditions
- Neonatal and perinatal conditions

Synonym
feeding tolerance

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: feeding tolerance, intermittent feeding, premature infants, semi-continuous feeding

Outcome measures

Primary outcome

tolerance of enteral feeding measured as the number of days before full enteral

nutrition is achieved

Secondary outcome

days to regain birth weight

growth (weight gain and knemometry)

days of intravenous fluids

incidence of feeding complications

catheter related sepsis

necrotizing enterocolitis

Study description

Background summary

Tube feeding is necessary for most premature infants less than 32 weeks because of their inability to coordinate sucking, swallowing, and breathing and the danger of aspiration. The conventional tube feeding method is intermittent bolus gavage feeding where a prescribed volume of milk is given over a short period of time, usually over 10 to 20 minutes by gravity, but several reports recommend semi-continuous or slow infusion feeding regimes too.
Clinical benefits and risks of semi-continuous versus intermittent nasogastric tube milk feeding cannot be reliably discerned from the limited information

available from randomized trials to date.
Studying the effects of the feeding method on feeding tolerance will lead to insight which feeding regime is best tolerated in preterm infants.

Study objective

To asses the effect of intermittent bolus nasogastric milk feeding versus semi-continuous milk feeding in preterm infants

Study design

single centre, randomized, prospective trial

Intervention

Intermittent bolus feeding

Study burden and risks

The two different regimes are widely used. To our knowledge there is no extra burden or risk associated with participation.
Our hypothesis is that patients fed intermittently will need less days to achieve full enteral nutrition.

Contacts

Public
Academisch Medisch Centrum

Dr. Molewaterplein 40
3015 GD ROTTERDAM
Nederland
Scientific
Academisch Medisch Centrum

Dr. Molewaterplein 40
3015 GD ROTTERDAM
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

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

Exclusion criteria

Congenital abnormalities gastrointestinal tract
No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2007
Enrollment:	250

Type:	Actual

Ethics review

Approved WMO Date:	30-11-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL13708.078.06