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

Submission date	Recruitment status	Prospectively registered
08/02/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
08/02/2007	Completed	Results
Last Edited	Condition category	[] Individual participant data
09/10/2014	Neonatal Diseases	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

#### **Acronym**

TOL

#### Study objectives

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.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approval received from the local ethics committee (Medical Ethical Committee), 13/11/2006, ref: METC-2006-268

#### Study design

Randomised placebo-controlled parallel-group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Premature infants

#### **Interventions**

Bolus intermittent nasogastric feeding versus semi-continuous milk feeding.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

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

#### Secondary outcome measures

- 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 necrotising enterocolitis

#### Overall study start date

05/02/2006

#### Completion date

05/02/2008

# **Eligibility**

#### Key inclusion criteria

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

#### Participant type(s)

Patient

#### Age group

Neonate

#### Sex

Both

## Target number of participants

250

#### Kev 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

#### Date of first enrolment

05/02/2006

#### Date of final enrolment

05/02/2008

# Locations

#### Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Centre Rotterdam Netherlands 3000 CB

# Sponsor information

#### Organisation

Erasmus Medical Centre (The Netherlands)

#### Sponsor details

Sophia Children's Hospital Dr. Molewaterplein 60 Rotterdam Netherlands 3015 GJ

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.erasmusmc.nl/#http://www.erasmusmc.nl/

#### **ROR**

https://ror.org/018906e22

# Funder(s)

### Funder type

Hospital/treatment centre

#### **Funder Name**

Erasmus Medical Centre (The Netherlands)

# **Results and Publications**

**Publication and dissemination plan**Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration