# The TOL-study: The effect of intermittent bolus nasogastric milk feeding versus semicontinuous 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

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# **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:	Actua

# **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