

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key 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)

ROR

<https://ror.org/018906e22>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration