ISRCTN42413683 https://doi.org/10.1186/ISRCTN42413683

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/02/2007	**Overall study status** Completed	
Last Edited 09/10/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Professor J B van Goudoever

Contact details
Erasmus Medical Centre
Sophia Children's Hospital
P.O. Box 2060
Rotterdam
Netherlands
3000 CB
+31 (0)10 463 6363
j.vangoudoever@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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)

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