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Efficacy of Minimal Enteral Feeding in neonates after surgical correction of gastroschisis, omphalocele or intestinal atresias

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
MEF protocol

Study objectives
With postoperative Minimal Enteral Feeding (MEF) the neonates can be fed completely enteral earlier than without MEF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre randomised placebo-controlled factorial 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
Duodenal and small bowel atresia, gastroschisis, omphalocele

Interventions
1. 6 x 2 ml feeding (formula or breast) through the nasogastric tube, followed by 30 minute tube closure
2. 6 x 30 minute tube closure without feeding
3. Start enteral feeding if daily gastric retention is less than 25 ml/day

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Number of days from the operation to enteral feeding of 120 ml/kg/day.

Secondary outcome measures
1. Weight gain on day 20 postoperative compared to birth weight
2. Number of coag. neg. staph. (CNS) sepsis episodes

Overall study start date
13/06/2002

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. All neonates with gastroschisis, omphalocele, duodenal and small bowel atresia who underwent surgical correction
2. Informed consent of the parents

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
40

Key exclusion criteria
1. No informed consent of the parents
2. Pre-operative bowel perforation
3. Per-operative need for a stoma

Date of first enrolment
13/06/2002

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
VU Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands) - Emma Children's Hospital

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