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

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| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/10/2014 | **Condition category**<br>Neonatal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr R. van Baren

**Contact details**
VU Medical Centre
De Boelelaan 1117
P.O. Box 7075
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 2424
r.vanbaren@amc.uva.nl

## 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