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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration