

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/10/2014	Condition category Neonatal Diseases	<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

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

<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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration