Efficacy of minimal enteral feeding in neonates after surgical correction of gastroschizis, omphalocele or intestinal atresias.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25686

Source
Nationaal Trial Register

Brief title
MEF protocol

Health condition

Neonates born with the following congenital malformations: gastroschsis, omphalocele and duodenal- or small bowelatresias, who are corrected surgically. Peri- and post-operatively they have a nasogastric tube for gastro-intestinal decompression. If gastric retentions disappear, enteral feeding can be started.

Sponsors and support

Primary sponsor: AMC
Meibergdreef 9
PO Box 22660
1100 DD Amsterdam
Phone +31 20 5669111
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Weight gain on day 20 postoperative compared to birthweight;

2. Number of coag. neg. staph. (CNS) sepsis episodes.

Study description

Background summary

In neonates born with gastroschisis, omphalocele or intestinal atresias who underwent surgical correction, postoperative MEF is compared to no MEF: number of postoperative days to complete enteral feeding and CNS sepsis episodes are probably less and the weightgain more in the group receiving MEF.

Study objective

With postoperative minimal enteral feeding (MEF) the neonates can be fed completely enteral earlier than without MEF.

Study design

N/A

Intervention

1. 6 x 2 ml feeding (formula or breast) through the nasogastric tube, followed by 30 min. tube closure;

2. Compared to 6 x 30 min. tube closure without feeding;

3. Start enteral feeding if daily gastric retention is less than 25 ml/day.

Contacts

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Eligibility criteria

Inclusion criteria

All neonates with gastroschsis, omphalocele, duodenal- and small bowel atresia who underwent surgical correction.
Informed consent of the parents.

Exclusion criteria

1. No informed consent of the parents;

2. Pre-operative bowel perforation;

3. Per-operative need for a stoma.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2002
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL229
NTR-old	NTR266
Other	: N/A
ISRCTN	ISRCTN96703143

Study results

Summary results

There are no publications on the efficacy of MEF after surgical corrections of congenital malformations. There are publications on MEF in prematures and term neonates on ventilation.