Defecation characteristics of the preterm and term neonate during the first years of life

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What is the normal stool frequency among premature and full term neonates?What is the normal colour of stools of the neonate?What is the normal consistency and amount of stools?What is the normal colonic transit time of premature and full term born...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30161

Source
ToetsingOnline

Brief title
Defecation and neonates

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, obstipation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: constipation, Defecation, neonate, premature

Outcome measures

Primary outcome

Primary variables:

Defecation frequency

Consistency of the stools

Colour of stools

Amount of stools

Secondary outcome

Secondary study parameters:

Colonic transit time (hours)

Duration of meconium stools (days)

Study description

Background summary

No well designed studies exist describing normal stool characteristics (defecation frequency, consistency and colour of stools) of premature, low-birth weight and term born infants. Furthermore, the duration of meconium stools before the appearance of normal stools is unknown. Although no normal data on stool characteristics exist some studies report that between 60-70% of the older children with constipation already had symptoms ofI constipation n the first months of life. To our opinion it is therefore of major importance to first describe the normal frequency of stools, consistency, amount and colour of the stools among preterm, dysmature and full term new born and subsequently

extrapolate these data to make a definition for constipation in the neonate.

Study objective

What is the normal stool frequency among premature and full term neonates?
What is the normal colour of stools of the neonate?
What is the normal consistency and amount of stools?
What is the normal colonic transit time of premature and full term born neonates?
Is it possible to define criteria for constipation of the neonate period based on the normal data we collect of the infants described above?

Study design

All newborn neonates who are admitted on the Units II and III of the AMC will be included if they meet the inclusion criteria (Premature and low birth weight neonates, gestational age 25-37 weeks and full term neonates born in our Academic Medical Center, gestational age 38-42 weeks).
Defecation frequency of all new born neonates will be recorded daily in standardized bowel diary from the first day of life until the first 4 weeks of life. Symptoms such as distended abdomen, vomiting, volume and type of feeding, first and last day of meconium stools will also be registered. Furthermore, stools will be visualised by taking pictures with a digital camera. Two doctors will independently evaluate the stool pictures. The photos will hopefully be used as standardized stool picture scoring system to evaluate the defecation pattern of neonates.

Furthermore, the colonic transit time will be evaluated by the use of Carmine red. Carmine red is an inert non-absorbed dye, which is bright red in colour and readily identifiable in neonatal stools. Side effects of Carmine red are not described in neonates. Three weeks and 6 weeks after birth neonates will receive 250 mg of Carmine red administered via a nasogastric tube. Only neonates who receive a minimum of 4 ml/ kg enteral feeding per day will get the carmine red. Colonic transit time is the time measured between administration and the first time that the dye is seen in the diapers of the neonate.

During the study period of three months, the newborn infants will be included into the study. The sample size will depend on the parents willing to participate into the study. We expect to include 60 preamture and 60 full term newborns.

Study burden and risks

There are no risks on participating in this study.

Parents will be asked to record the defecation pattern of their child in a standardized stool diary for seven subsequent days. This will be done on t = 2, 6, 9,12, 24 and 36 months.
The parents of healthy full term infants will be asked to administer Carmine red twice, on week 3 and week 6 after birth. The premature neonate will receive Carmine red via the nasogastric tube.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Premature and low birth weight neonates (Gestational age 25-37 weeks)
Full term neonates born in our Academic Medical Center (Gestational age 38-42 weeks)

Exclusion criteria

Gastrointestinal surgery (anal atresia, Hirschsprung's disease)
Neurological disease (Spina bifida)
Metabolic disease (CF, Hypothyreoidism)
Congenital disorders (Down syndrome)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL12890.018.06