Double-blind randomised evaluation of clinical tolerance (taste) of PEG 4000 and PEG 3350 in children with constipation

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Evaluate which PEG (4000 or 3350) is most preferred by children.Evaluate whether a preferable taste of the drug can lead to a better compliance and subsequently to a better success percentage of the treatment of childhood constipation.

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

Summary

ID

NL-OMON30493

Source
ToetsingOnline

Brief title
Clinical tolerance of PEG 4000 and PEG 3350

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Childhood constipation, PEG 3350, PEG 4000, Taste

Outcome measures

Primary outcome

Primary outcome parameters:

* PEG Preference (T=0)

* Constipation

* Compliance

Lemonade add-on is considered as a non-compliance towards the product when seen

in a frequency exceeding the 40%

Secondary outcome

Secondary outcome parameters

* Frequency of lemonade as an add-on

* Time required for administration of the drug

* PEG Preference (T= 4)

Study description

Background summary

Functional childhood constipation occurs in 6-30% of the children in the western World. Nowadays polyethylene glycol (PEG) is becoming the first choice drug for many paediatricians to treat constipation. The pediatricians can choose from different PEG products PEG 4000 or PEG 3350. In general, it is well/known that children do not like the taste of drugs. Few data in constipated children show that PEG 4000 is better tolerated than Lactulose. But a comparison of tolerance between two different PEG products in constipated children has yet to be evaluated.

Our hypothesis is that compliance improves when children can choose (after tasting) the medication themselves.

Study objective

Evaluate which PEG (4000 or 3350) is most preferred by children.

Evaluate whether a preferable taste of the drug can lead to a better compliance and subsequently to a better success percentage of the treatment of childhood constipation.

Study design

All children aged 4-12 and first seen in our outpatient clinic of the Emma Children Hospital of the AMC presenting with functional constipation will be asked for participation. After informed consent patients will be randomised to either choose a PEG or to get one of the 2 PEGs (Forlax or Movicolon) in a dose of 0.5 g/kg randomised by a computer programme.(4) All children and their parents will be asked to complete a bowel diary to note the frequency of bowel movements as well as symptoms like abdominal pain and nausea. The time taken to administer the drug as well as the liquid in which the drug will be solved is noted in the diary. Parents will be instructed to first try to solve the drug in water. If the child refuses or it takes over an hour to administer the drug they may solve it in lemonade. After 2 weeks we will evaluate the clinical condition of the child by physical examination and by the information from the bowel diaries. At week 4, children who did not choose at the start of the study will also get the chance to taste a PEG and inform us about his/ her preference. Also children who chose the drug at the start of the study will again taste the drugs and give their preference. Besides tasting the drugs, children will be examined and bowel diaries will be evaluated at week 4. This third visit will be the end of this study. Children will further be treated in our outpatient clinic for their complaints after completing the study.

Intervention

Not applicable

Study burden and risks

There is no burden for the patient. However, patients taste the PEGs once or twice during a test requiring less than 5 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Functional constipation as defined by the Rome III criteria
Age 4-12 years

Exclusion criteria

Children who received PEG 4000 or PEG 3350 during the last 2 weeks before intake.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	427
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	NL15052.018.07