Does supported faecal production accelerates the final diagnosis in children with acute abdominal pain?

Published: 16-05-2013
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The objective of this research is to see if this way of treating a patient ensures a quicker diagnosis, which results in lessabdominal pain for the patient.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON38636

Source
ToetsingOnline

Brief title
Supported faecal production and the diagnosis of acute abdominal pain

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation, obstruction of the intestines

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Constipation, Non-specific abdominal pain, Treatment

Outcome measures

Primary outcome

The primary outcome is diminished acute abdominal pain, this will be measured

during the anamnesis and physical

examination by using the *comfort scale* or the VAS-measurement and the ammount

of used painkillers.

Secondary outcome

The time needed for reaching the final diagnosis.

Study description

Background summary

In children presented with acute abdominal pain, a relative substantial group remains with a nonspecific cause. A
suggested part of this group suffers from acute or chronic constipation.
The diagnose of constipation is difficult, because it needs multiple evaluations, inclusive abdominal x-rays and various
histories of last defecations time. Laxantives are the treatment of choice for constipation.

Study objective

The objective of this research is to see if this way of treating a patient ensures a quicker diagnosis, which results in less
abdominal pain for the patient.

Study design

A randomized control interventional trial with and without treatment

Intervention

If there is still doubt after clinical examination and laboratory results (where an additional blood sample is taken) if the patient has appendicitis, then he or she will be randomised. In this study half of the patient group will receive laxantives and clysmata, which is the treatment for constipation. The other half of the group will not receive a treatment in the meantime. Both groups will be asked to come back the next day for a new clinical examination. During the clinical examination the pain score will be measured by using the "comfort scale" or the VAS measurement, also the ammount of use of painkillers will be analyzed

Study burden and risks

For this study the patients who have constipation benefits from the given intervention, because laxantives and clysmata is the standard treatment for constipation. Laxantives and clysmata are not a burden for the health of the children.

Substudy:
The extra blood sample of 6 ml will be collected with the routine blood sampling which takes place in all children with suspected appendicitis. Therefore, no extra venapuncture is necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

All patients between 5 and 18 years, who are referred by first line health care with the suspicion of acute appendicitis.

Exclusion criteria

Severe co-morbidity like malignancy, resent abdominal surgery and known inflammatory bowl disease.
Pregnancy

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2014
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Colex clysmata
Generic name:	Sodiumphosphate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Does not exist
Generic name:	Sorbitol clysmata
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Forlax
Generic name:	Macrogol 4000
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Forlax junior
Generic name:	Macrogol 4000
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2013-000498-56-NL
CCMO	NL44710.042.13

Study results

Date completed:	06-11-2017
Actual enrolment:	98