Fecal calprotectin guided referral strategy in children in primary care

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Point of care testing with Fcal POCT will reduce substantial the referral rate of children with chronic GI symptoms to the paediatrician.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON20247

Source
Nationaal Trial Register

Brief title
DOK 2.0

Condition

- Gastrointestinal signs and symptoms

Health condition

Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: Buhlmann Group

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Proportion referrals in children with chronic GI disorders within 6 months after initial presentation in primary care.

Secondary outcome

Parental concerns and satisfaction, impact of symptoms on daily functioning, quality of life, use of health services, and cost-effectiveness during 6 months follow-up.

Study description

Background summary

Rationale: Children with chronic gastrointestinal symptoms are common in primary care. Whereof 90% suffer from functional gastrointestinal disorders (FGID), i.e. gastrointestinal symptoms without a known medical explanation. Inflammatory bowel disease (IBD) needs to be eliminated before diagnosing FGID. It is a diagnostic challenge to differentiate between FGID and IBD, because the clinical presentations can be very similar. The impact of the promising faecal calprotectin (FCal) test that may reduce blood tests and referrals without missing a child with IBD is not yet evaluated. Additionally, it is unknown whether testing with FCal in primary care will improve clinical outcomes of the children, e.g. patients concern and reduction in the impact of gastrointestinal symptoms. Objective: To assess whether FCal point-of-care (POC) testing in primary care reduces referral rates of children with chronic gastrointestinal symptoms to the paediatrician, improves parental concerns and satisfaction, impact of symptoms on daily functioning, quality of life, and cost-efficiency of care, as compared to usual care. Study design: Cluster randomised controlled trial with 6 months follow-up. Study population: Children, aged 4 to 18 years, presenting with chronic diarrhoea or recurrent abdominal pain in primary care. Intervention: One group of general practitioners (GPs) will be instructed to use FCal POCT test and be subjected to an accredited training with instructions on indication, execution, interpretation, communication, reporting and follow-up of FCal POCT (intervention group). The other group of GPs will be instructed to provide care as usual according to the Dutch Society of GPs guideline for children with abdominal pain, which recommends no testing of FCal (control group). Main study parameters/endpoints: Primary outcome is the proportion of referrals in children with chronic GI symptoms within 6 months after index consultation in primary care. Secondary outcomes are parental concerns

and satisfaction, impact of symptoms on daily functioning, quality of life, use of health services, and cost-effectiveness during 6 months follow-up.

Study objective

Point of care testing with Fcal POCT will reduce substantial the referral rate of children with chronic GI symptoms to the paediatrician.

Study design

Measurements will be at baseline, 3 and 6 months follow-up.

Intervention

The use of FCal POCT in primary care. The general practitioners will receive an online training with instructions on indication, execution, interpretation, communication, reporting and follow-up of FCal POCT.

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

- children, aged 4 to 18 years, with - chronic diarrhoea (soft or watery stool, matching scores 5–7 of the Bristol Stool chart, for >2 weeks or >2 episodes of 3 days in the past 6 months) OR - recurrent abdominal pain (>2 episodes of 3 days in the past 6 months)

Exclusion criteria

- a history of chronic organic gastrointestinal disease - an endoscopic evaluation, referral to specialist care or FCal result within the preceding 6 months - difficulty in understanding questionnaires due to cognitive impairment or language problems

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2019
Enrollment:	406
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Restricted access. Data will be shared upon request. Details are described in Data

Management Plan on DMPonline.

Ethics review

Positive opinion

Date:	03-10-2019
Application type:	First submission
Review commission:	nWMO adviescommissie UMC 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
NTR-new	NL7690
Other	ZonMw : 852001930

Study results