DarmOnderzoek bij Kinderen

Gepubliceerd: 26-04-2019 Laatst bijgewerkt: 03-03-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	Maagdarmstelseltekenen en -symptomen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20247

Bron
Nationaal Trial Register

Verkorte titel
DOK 2.0

Aandoening

- Maagdarmstelseltekenen en -symptomen

Aandoening

Inflammatory Bowel Disease

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: Buhlmann Group

Onderzoeksproduct en/of interventie

- Medische hulpmiddelen

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Kinderen (2-11 jaar)
Kinderen (2-11 jaar)
Adolescenten (12-15 jaar)
Adolescenten (12-15 jaar)
Adolescenten (16-17 jaar)
Adolescenten (16-17 jaar)

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Diagnostiek

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-10-2019
Aantal proefpersonen:	406
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

Restricted access. Data will be shared upon request. Details are described in Data Management Plan on DMPonline.

Ethische beoordeling

Positief advies

Datum:	03-10-2019
Soort:	Eerste indiening
Toetsingscommissie:	nWMO adviescommissie UMC Groningen

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7690
Ander register	ZonMw : 852001930

Resultaten