Multicenter, gerandomiseerd, placebo-gecontroleerde studie naar mebeverine in kinderen met PDS (prikkelbare darm syndroom) of FAP-NOS (functionele buikpijn - niet anders gespecificeerd).

Gepubliceerd: 06-02-2019 Laatst bijgewerkt: 15-05-2024

The effect of mebeverine on abdominal pain intensity and frequency in children with irritable bowel syndrome or functional abdominal pain – not otherwise specified will be effective.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Maagdarmstelseltekenen en -symptomen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23931

Bron
Nationaal Trial Register

Verkorte titel
Duski

Aandoening

- Maagdarmstelseltekenen en -symptomen

Aandoening

IBS and FAP-NOS

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Mylan B.V.
Overige ondersteuning: Stichting Kindermotiliteit

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The proportion of patients with > 50% reduction of their abdominal pain intensity and pain frequency after 8 weeks of therapy

Toelichting onderzoek

Achtergrond van het onderzoek

Irritable bowel syndrome (IBS) and functional abdominal pain – not otherwise specified (FAP-NOS) are common disorders in children. They are associated with a reduced quality of life and an increased risk for psychiatric disorders. Therapeutic options are symptomatic pharmacological treatment to reduce pain, often together with dietary advice, or psychological therapies. Mebeverine is an antispasmodic agent that is often used as symptomatic pharmacological treatment in these children, however the effectiveness of mebeverine (tablet/capsule) has never been studied properly in children and studies conducted with mebeverine suspension in children were uncontrolled. Objective: The primary objective of this study is to investigate the effectiveness of mebeverine on abdominal pain reduction in children with IBS or FAP-NOS. Secondary objectives are to study to investigate the effect of simple advices to child and parents during an observational period. Study design: This multicentre study consists of a baseline period of 4 weeks followed by a randomised placebo-controlled trial of 8 weeks duration. Study population: The study population consists of 284 randomised children between 12 and 18 years diagnosed with irritable bowel syndrome or functional abdominal pain – not otherwise specified according to the Rome IV criteria. Intervention: Patients will be randomly allocated to: mebeverine HCl retard 200 mg (twice daily) or to placebo capsules (twice daily). Main study parameters/endpoints: The main outcome parameter is the number of patients with >50% reduction of their abdominal pain intensity and frequency after 8 weeks of therapy. The secondary outcomes are: the effect of reassurance, explanation and simple dietary and behavioural advice on abdominal pain frequency and intensity and on adequate relief, the number of patients with adequate relief after 8 weeks of therapy, change in IBS/ FAP-NOS symptoms, change in Quality of Life scores, change in depression and anxiety scores, school absences during and after the treatment, use of rescue medication during the treatment,

somatisation scores, the incidence of adverse events during the treatment.

Doel van het onderzoek

The effect of mebeverine on abdominal pain intensity and frequency in children with irritable bowel syndrome or functional abdominal pain – not otherwise specified will be effective.

Onderzoeksopzet

Visit 1 = 0 weeks Visit 2= 4 weeks TC = 8 weeks Visit 3 = 12 weeks Visit 4 = 16 weeks

Onderzoeksproduct en/of interventie

Mebeverine

Contactpersonen

Publiek

Amsterdam UMC, lacatie AMC
Koen Vermeijden

Wetenschappelijk

Amsterdam UMC, lacatie AMC
Koen Vermeijden

Deelname eisen

Leeftijd
Adolescenten (12-15 jaar)
Adolescenten (12-15 jaar)
Adolescenten (16-17 jaar)
Adolescenten (16-17 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All children aged between 12 and 18 years diagnosed with irritable bowel syndrome or

functional abdominal pain – not otherwise specified according to the Rome IV criteria will be invited to participate. The Rome IV criteria form the internationally accepted standard for defining functional gastrointestinal disorders like irritable bowel syndrome and functional abdominal pain – not otherwise specified.1 Before inclusion, all patients undergo routine laboratory testing to exclude underlying organic disorders: complete blood cell count, C-reactive protein, celiac screening (anti-transglutaminase antibodies and IgA), fecal screening on Giardia lamblia if patient presents with diarrhea, and on calprotectin in case an Inflammatory Bowel Disease is suspected. The need for further diagnostic testing is left to the discretion of the treating physician. Finally, according to a recently published guideline by the Rome Foundation for the design of pharmacological clinical trials in children, patients are required to have an average daily pain rate of ≥2 on the Wong Baker Faces Pain Scale. This is a validated pain scale to measure pain intensity. In addition, Informed Consent by both parents and by children aged ≥ 12 years is a necessity before children can be included in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Current treatment by another health care professional for abdominal symptoms • Previous use of mebeverine • Known hypersensitivity to the active substance or to any of the excipients ((magnesium stearate, polyacrylate dispersion , talc, hypromellose, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion , glycerol triacetate, gelatine, titanium dioxide (E171), shellac (E904), propylene glycol, ammonia solution (concentrated), potassium hydroxide, iron oxide black (E172)). • Unintentional weight loss greater than or equal to 5% of their body weight within the last 3 months • Gastrointestinal blood loss • Recurrent or unexplained fevers • Decreased growth velocity • History of previous abdominal surgeries in the past 3 months • Rome IV criteria diagnosis of functional constipation • Children who tested positive for bacterial or parasites infections • Carbohydrate malabsorption, diagnosed either clinically (2 weeks exclusion diet with resolution of symptoms) or with proper testing (breath test). Children with carbohydrate intolerance who continue to have IBS symptoms while on an exclusion diet can still be included • Significant chronic health condition requiring specialty care (e.g., lithiasis, ureteropelvic junction obstruction, sickle cell, cerebral palsy, hepatic, hematopoietic, renal, endocrine, or metabolic diseases) that could potentially impact the child’s ability to participate or confound the results of the study • Known diagnosis of cystic fibrosis • Known diagnosis of porphyria • Known concomitant organic gastrointestinal disease • Current use of drugs which influence gastrointestinal motility, such as erythromycin, azithromycin, butyl scopolamine, domperidone, peppermint oil capsules, and Iberogast. • Insufficient knowledge of the Dutch language • Pregnancy or current lactation. Women with childbearing potential must have a negative urine pregnancy test within 7 days prior to first dose of study treatment

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-11-2018
Aantal proefpersonen:	325
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	06-11-2017
Soort:	Eerste indiening
Toetsingscommissie:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

mecamc@amsterdamumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55563
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7508
CCMO	NL55301.018.15
OMON	NL-OMON55563

Resultaten