

Behandeling van Obstipatie bij Kinderen

Gepubliceerd: 08-09-2014 Laatste bijgewerkt: 18-08-2022

We expect paediatric pelvic physiotherapy in addition to conventional treatment to be more (cost)- effective than conventional treatment alone, after 8 months follow-up.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23225

Bron

Nationaal Trial Register

Verkorte titel

BOKi

Aandoening

child, constipation, physiotherapy, kinderen, obstipatie, fysiotherapie

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), department of general practice

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Treatment success at 8 months follow-up.

Treatment success is defined as the absence of constipation according the QPGS ROME III questionnaire without the use of laxatives.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Education, dietary advice, toilet training and laxative treatment is currently recommended as the first choice therapy for children with functional constipation in primary care (conventional treatment). Paediatric pelvic physiotherapists claim to obtain good results with their treatment and they already treat many children with functional constipation. However because a lack of randomised controlled trials, paediatric pelvic physiotherapy is not yet evidence-based.

Objective: The primary objective is to study the effect of paediatric pelvic physiotherapy in addition to conventional therapy on the number of patients with treatment success in children aged 4-17 years in primary care with functional constipation in comparison to conventional treatment alone.

Study design: Randomised controlled trial with a follow-up of 8 months.

Study population: Children aged 4-17 years with functional constipation in primary care.

Intervention: The therapy will consist of education about defecation, toilet training, breathing exercises, training of the pelvic floor muscles, and training of the abdominal muscles. This will be added to the conventional treatment of functional constipation.

Main study parameters/endpoints: Primary outcome measure is treatment success at 8 months follow-up. Treatment success is defined as the absence of constipation according the ROME III criteria for functional constipation; without using laxative treatment in the past 4 weeks. Secondary outcome measures are treatment success at 4 months, absence of constipation irrespective of laxative use at 4 and 8 months, quality of life and costs.

Doel van het onderzoek

We expect paediatric pelvic physiotherapy in addition to conventional treatment to be more (cost)- effective than conventional treatment alone, after 8 months follow-up.

Onderzoeksopzet

Follow up visits will be at 4 and 8 months.

Onderzoeksproduct en/of interventie

Paediatric pelvic physiotherapy will be given by a certified paediatric physiotherapist with additional education in pelvic physiotherapy, according to the standards of the Dutch Pelvic Physiotherapists Organization (NVFB). Treatment will start within one week after randomisation. The therapy will consist of assessment of motor development, extensive physiotherapy training, breath control, pelvic floor training, core stability training and abdominal massage. It includes isometric training of the abdominal muscles, defecation stimulating exercises on the toilet, and relaxation and diaphragmatic breathing exercises. The paediatric physiotherapist will decide on treatment frequency and duration (usually 3-6 sessions). We will not use a standard protocol for the physiotherapeutic intervention but chose a more flexible, pragmatic approach in which the participating pediatric physiotherapists tailor their treatment to the need of each child, as would be the case in normal practice.

To gain insight in the treatment techniques and treatment duration in our study population pediatric physiotherapists register their treatment and the number of visits for each patient on a structured form.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children aged 4 to 17 years
- Diagnosis of functional constipation by GP or Paediatrician
- Informed consent of both parents and the child (if aged ≥ 12 years)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Physiotherapy or urotherapy for constipation in the past 3 years
- Psychopathology disabling protocol adherence
- Severe/terminal illness

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	180
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 08-09-2014

Soort: Eerste indiening

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	NL4654
NTR-old	NTR4797
Ander register	ZonMW : 80-83700-98-41027

Resultaten