Improving Adherence by Guiding Inhalation via Electronic monitoring in children

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It is expected that providing children with active qualitative feedback on performed inhalations will directly improve therapy adherence and inhalation technique and therefore will increase asthma control in both short and long term.

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

Samenvatting

ID

NL-OMON25807

Bron
NTR

Verkorte titel
IMAGINE I

Aandoening

Uncontrolled asthma in children

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente (MST)
Overige ondersteuning: Fondsenwerving MST
Stichting Asthma Bestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: It has been shown that therapy adherence is suboptimal in children with asthma limiting the effect of inhaled medication. In this study, the effect of providing qualitative feedback on therapy adherence and inhalation technique is assessed.

Objective: The primary objective of this study is to improve asthma control in children with uncontrolled asthma by trying to improve their therapy adherence and inhalation technique through feedback.

Study design: The first phase consists of a 4 week observational study period, where the therapy adherence and inhalation technique of the patients is assessed. Parameters related to poor adherence are determined in this phase. The second phase lasting 6 weeks consists of a randomised controlled trial where one group receives immediate smart feedback on therapy adherence and inhalation technique and the other group does not receive feedback. Finally, in phase 3, the lasting effect of qualitative feedback will be assessed. This phase can be seen as a follow-up and patients will receive treatment depending on asthma control and therapy adherence & inhalation technique according to standard care and GINA recommendations. The options consist of: no change in medication, step-up therapy, step-down therapy or consultation with the paediatrician. Feedback will be ceased for all subjects during phase 3.

Study population: The study population consists of children with uncontrolled asthma in the range of 6 until 18 years of age. The randomisation process will be stratified for age with a cut-off at 12 years old and use of nasal corticosteroids.

Intervention: For this study, a RespiroTM add-on device is attached to the current inhaler therapy to measure critical parameters such as date and time of inhalation, peak flow, duration of the inhalation. Non-critical parameters as orientation of the inhaler, and opening and closing the inhaler will also be assessed.

Main study parameters/endpoints: The main study parameter is clinical improvement in patients with uncontrolled asthma. Clinical improvement is assessed by FEV1, lung function variability and the (c-)ACT score.

Doel van het onderzoek

It is expected that providing children with active qualitative feedback on performed inhalations will directly improve therapy adherence and inhalation technique and therefore will increase asthma control in both short and long term.

Onderzoeksopzet

The study is seperated in 3 phases. Phase 1 lasts 4 weeks and phases 2 and 3 both last 6 weeks. Lung function will be assessed at the end of each phase in MST by spirometry and a(n) (c-)ACT questionnaire. An interim analysis will be performed after halfway through the inclusion at the end of phase 2 to assess the true effect of the qualitative feedback.

Onderzoeksproduct en/of interventie

Providing feedback over inhalation technique and therapy adherence by an add-on device provided by AMIKO

Contactpersonen

Publiek

Medisch Spectrum Twente
Martijn Oude Wolcherink

N/A

Wetenschappelijk

Medisch Spectrum Twente
Martijn Oude Wolcherink

N/A

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children aging from 6-18 years old.
- Children who suffer from uncontrolled asthma.
- Children are under treatment by either the ZGT and MST
- Children who have performed a lung function test in the past 6 months or are scheduled for one

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Children who are unable to speak or understand the Dutch language. This also applies for parents of all children below the age of 12.
- Children whos medication cannot be delivered by the Nexthaler, Ellipta or Spiromax.
- Children with a chronic disease other than asthma that can influence the lung function.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	68
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	29-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50093
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7705
CCMO	NL69291.044.19
OMON	NL-OMON50093

Resultaten

Samenvatting resultaten
No publications yet