# "What children want and what they do", a real life study of how long children inhale their asthma medication correctly in the home situation, monitored with homemade video clips with the iPad®.

Gepubliceerd: 17-03-2014 Laatst bijgewerkt: 13-12-2022

1- Their is a difference in decline of inhalation technique in children between different devices. 2-The decline in inhalation technique is greater in the home situation compared with the live check in front of a health care professional.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

#### ID

NL-OMON20232

Bron NTR

Verkorte titel Inhalation technique

#### Aandoening

- Children aged 6-18 years
- Asthma
- Inhalation technique

## Ondersteuning

**Primaire sponsor:** Stichting Pediatrisch Onderzoek Twente, Medical Centre Twente **Overige ondersteuning:** Stichting Pediatrisch Onderzoek Twente and TEVA Pharma

## **Onderzoeksproduct en/of interventie**

#### Uitkomstmaten

#### Primaire uitkomstmaten

Differences in sustainability of inhalation technique of Diskus® and Autohaler® in the home situation. This will be measured with the inhalation checklist for the Diskus® and Autohaler®. Endpoint will be the difference in score for the critical errors between both devices in the home situation.

## **Toelichting onderzoek**

#### Achtergrond van het onderzoek

Asthma is the most common chronic lung disease in childhood and characterized by airway inflammation, airway hyper responsiveness and reversible airflow obstruction. Management of asthma exists of educational and therapeutic interventions. Educational interventions are necessary to improve adherence, inhalation technique and self-management of patients1-3.

Correct use of inhalers is essential in asthma treatment, however they are often used suboptimal3-7. Repeated instructions lead to a better technique in the doctor's office 4,5,7,8, but it is not sure that this reflects the way patients use their inhalers at home. Live demonstration of inhalation technique shows how well a child can perform in front of a health care professional and their caregivers. Parents regularly report that the technique in the home situation is worse than the child shows at the outpatient clinic, potentially reducing the therapeutic benefit and increasing the risk of adverse events. Both outcomes may in turn compromise adherence 7-10.

There are several training tools available for training the patients in the correct use of pressured Metered-Dose-Inhalers (pMDI's) and Dry Powder Inhalers (DPI's). One of these tools, the Inhalation Manager®, offers the opportunity for computer-based measurement of the entire inspiratory maneuver with several devices11,12. This can help during instruction sessions to improve and check objectively the quality of the inhalation technique13. In recent years children have become used to communicate via digital channels, for example by sending video clips to each other. The introduction of Wi-Fi, tablets and smart phones have made it easy to connect digitally wherever you are. This gives us the opportunity to investigate the inhalation technique in the home situation.

Two inhalation technique studies in children have checked pMDI with Valved Holding Chamber (VHC) to several DPI's as used in the doctor's office4,8. In the CHESS-study8 children were instructed to send a video clip once a week of the recorded inhalation technique that was scored with standardized checklists and provided with feedback through e-mail. There was already a good inhalation technique at the start of the study, for respectively DPI and pMDI-VHC 82,5% and 86,7%, due to an intense training program in asthma management before starting this study. Therefore the inhalation technique improved for respectively DPI and pMDI-VHC 92,8% and 94% during the year. However the number of uploaded videos was low, only one third of the expected videos were uploaded to the web site. Also this study did not analyze the difference in inhalation technique at the doctor's office compared with the home situation.

The study of Kamps et al showed that after three instruction sessions during approximately 24 weeks all children using DPI or pMDI-VHC improved their inhalation technique as demonstrated in a hospital. At the initial visit only 25% of the newly referred DPI users and 76% of the pMDI-VHC users showed a correct inhalation technique. At the end of the study period the inhaler technique improved to respectively to 95-100%5.

To our knowledge there is no study that has assessed daily inhalation technique in children in the home situation comparing two often prescribed breath actuated devices.

The aim of this study is to investigate the sustainability of the inhalation technique of two often prescribed devices in children aged 6-18 years in the home situation. Secondary aims are to investigate the reliability of inhalation technique as demonstrated in a hospital compared with inhalation technique as videotaped in the home and to investigate the influence of the use of the Inhalation Manager® on the preference for device of a Nurse practitioner

#### Doel van het onderzoek

1- Their is a difference in decline of inhalation technique in children between different devices.

2-The decline in inhalation technique is greater in the home situation compared with the live check in front of a health care professional.

#### Onderzoeksopzet

- Difference in critical errors for both devices in the home situation in %

- How many days makes the child the same critical error with each device during the observation period in %

- How many children make the same critical error(s) with each device in the home situation in %

- How many children make the same critical errors during the second hospital visit compared with the home made videos in %

- How many times changes the device preference in the children after the observation period in %

- Which attributes of the devices play a role in the decision making in device preference of the children during visit 1 and 2 in %

- Is their a difference in device preference in the children after the observation period in %

- How many times does the device preference of the Nurse Practitioner chances after using the Inhalation manager in %

#### **Onderzoeksproduct en/of interventie**

Making a video clip of the inhalation technique using the iPad with the Fluticasone Diskus and

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Beclometasone Autohaler once a day during a period of one month

## Contactpersonen

#### **Publiek**

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#### Wetenschappelijk

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## **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical history of asthma symptoms.

- Age 6 through 18 years.

- Children who are starting with inhaled corticosteroid medication or have the age and maturity to switch their inhaled corticosteroid medication to Diskus® or Autohaler®.

- Ability to perform inhalation technique after instruction with Diskus® and Autohaler®.
- Ability to record and send video clips of inhalation technique with an iPad®.

#### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Children who used or had been trained before with Diskus or Autohaler®.

# Onderzoeksopzet

#### Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

#### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	34
Туре:	Verwachte startdatum

# **Ethische beoordeling**

Positief advies Datum: Soort:

17-03-2014 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	NL4302
NTR-old	NTR4447
Ander register	NL47658.044.14 : ABR-register: 47658

# Resultaten

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