“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®.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20232

Source
NTR

Brief title
Inhalation technique

Health condition

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

Sponsors and support

Primary sponsor: Stichting Pediatrisch Onderzoek Twente, Medical Centre Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Twente and TEVA Pharma

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

• Differences in sustainability of inhalation technique between Flixotide Diskus® and Qvar Autohaler®, scored with the inhalation checklist, as demonstrated in the hospital with inhalation technique as videotaped in the home. Endpoint will be the difference in score for critical errors between inhalation technique demonstrated in the hospital with inhalation technique as videotaped in the home.
• Difference in device preference in children at visit 1 and 2 measured with the self administered questionnaire for device preference. The endpoint will be the difference in outcomes for preference of device attributes between visit 1 and 2.
• Difference in what determines the choice of device for a child at visit 1 and 2 measured with the self made questionnaire for importance and satisfaction of device attributes. The endpoint will be the difference in outcomes for importance and satisfaction of device attributes between visit 1 and 2.
• Difference in device preference of the NP at visit 1 and 2 before and after the use of the Inhalation manager®. The endpoint will be the difference for device preference before and after using the Inhalation manager®.

Study description

Background summary

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

Study objective

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.

Study design

- 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 %

Intervention

Making a video clip of the inhalation technique using the iPad with the Fluticasone Diskus and Beclometasone Autohaler once a day during a period of one month

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Eligibility criteria

Inclusion criteria

- 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®.

Exclusion criteria

- Children who used or had been trained before with Diskus or Autohaler®.
- Other cardiac or pulmonary comorbidity

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4302
NTR-old	NTR4447
Other	NL47658.044.14 : ABR-register: 47658

Study results