What children want and what they do: a real life study of the consistency and sustainability of the inhalation technique monitored with homemade video clips.

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Main objective: To investigate 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®. Secondary objectives: * To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON41700

Source
ToetsingOnline

Brief title
Inhalation technique

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Obstructive Pulmonary Disease; Ashma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede,TEVA Pharma

Intervention

Keyword: Asthma, Children, Home monitoring, Inhalation technique

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 the percentage of at least one critical errors, on one or more days, with Autohaler® versus Diskus® 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 techniques 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 outcome for device preference 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 patients.
Correct use of inhalers is essential in asthma treatment, however they are often used suboptimal. Repeated instructions lead to a better technique in the doctor*s office 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.
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 devices. This can help during instruction sessions to improve and check objectively the quality of the inhalation technique.
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 office. In the CHESS-study 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%.
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 differences in 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

Main objective:
To investigate 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®.

Secondary objectives:
* To investigate the relationship of inhalation technique as demonstrated in the hospital with inhalation technique as videotaped at home in asthmatic children.
* To investigate the preference of device for a child before and after the study period.
* To investigate what determines the choice of device for a child before and after the study period.
* To investigate the preference of device of the Nurse Practitioner (NP) before and after the use of an Inhalation Manager®.

Study design

This study will be a prospective observational study.
Children will be randomly instructed to use the Diskus® and Autohaler® or vice versa once daily by a NP. Group 1 will use Flixotide 100 µg Diskus® in the morning and Qvar 100 µg in the evening, group 2 vice versa. Children will

receive a Flixotide 100µg Diskus® and Qvar 100µg Autohaler® to use at home after showing a good inhalation technique for both devices. Children are instructed at visit 1 how to record and send their daily video clips of the inhalation for both devices with an iPad®. If the child does not e-mail his/her inhalations he/she will receive an electronic reminder from the NP on the IPad®. If a child does not mail the video clips for more than three consecutive days or more than three times a week he/she will be excluded from this study. After 4 weeks the child is invited to the outpatient clinic to demonstrate his/her inhalation technique with both devices. The inhalation technique will be scored with standardized inhalation protocols designed by the Lung Alliance Netherlands (LAN) by the NP.

Study burden and risks

The risks of participation are considered minimal. Both inhaled corticosteroids are registered for children aged 6-18 years old and proven to be of therapeutic benefit for children with the diagnosis asthma. Risk for side effects is equal for both inhaled steroids, also most of the children who will be included in this study already used inhaled corticosteroids as maintenance medication in the same dosage.
Patients have to make a daily recording of their inhalation with both devices. They can make the recording with the iPad® which they can use freely during this research. Recording the inhalation technique with both devices and sending the video to the NP will take five minutes per day. After four weeks using both devices children come to the outpatient clinic for evaluation. The benefit is that the switch to a new inhaler device can be based on the performance of inhalation technique in the home situation. Also we will see if the live check, which is the appropriate in the treatment of asthma, gives enough information to choose the correct device for the child.
Besides our expectation is that participation in the study will result in better adherence to maintenance medication and improve control of asthma, implying that this study may not alone be of diagnostic but also of therapeutic relevance. This study has to be performed in children with asthma, because pulmonary deposition of inhaled medication in children is easily compromised as children have smaller airways and lower inspiratory flow. Inhaled medication has been developed and evaluated for adults.
As far as we know there are no studies that have compared the rate of deterioration of inhalation technique in children using Diskus® or Autohaler® in the home situation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2014
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-02-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-12-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	4447
CCMO	NL47658.044.14