Investigation of the applicability of dry powder inhalation in school children

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON37634

Source
ToetsingOnline

Brief title
Dry powder inhalation in school children

Condition

- Respiratory tract infections

Synonym
cystic fibrosis, mucoviscidosis

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Royalties van de Novolizer (inhalator die door de betrokken afdeling van de RUG is ontwikkeld en die op de markt is gebracht)

Intervention

Keyword: Children, Dry powder inhalation, Inhaler design, Inhaler optimisation

Outcome measures

Primary outcome

The main study parameter is the ability of a child to understand how to use the inhaler correctly.

Secondary outcome

The parameter that describes whether or not a child is capable of using the inhaler correctly is the pressure drop (s)he creates over the inhaler upon inhalation, from which various inspiratory parameters can be calculated. Furthermore, the presence of a blockage in the mouth upon inhalation will be observed as function of the inhaler design (mouthpiece and resistance).

Study description

Background summary

The department of Pharmaceutical Techonology and Biopharmacy works on improving drug delivery to the lungs, mainly focussing on severe diseases, e.g. cystic fibrosis (CF). CF is a chronic, life shortening, genetic disease and the complications associated with this disease occur already at a young age. One of these are ever-recurring lung infections, which are the main cause for the patient*s early death. Early, effective treatment might prevent or postpone the transition into a chronic infection. Currently, lung infections in CF are treated with nebulised antibiotics. However, the currently used nebulisers have several disadvantages, like a low lung deposition efficacy and a long administration time (up to 20-30 min twice daily). Therapy with a dry powder inhaler (DPI) has the potential to be superior over nebulisation, but its applicability in children has not been tested systematically yet. The development of a DPI that better suits the needs of children, based on their intellectual and inspiratory capacities, is essential. In this study, we will investigate the applicability of dry powder inhalation in school children in

order to enable us to develop a DPI specifically for this patient group.

Study objective

The primary objective is to determine from what age on children can operate a test inhaler correctly (handling). The secondary objectives are to determine whether children can generate a sufficiently large airflow and volume through the test inhaler for dispersion of a medicinal powder in relationship to their age or height, and which resistance and type of mouthpiece are most favourable for, respectively accepted by children.

Study design

Non-therapeutic observational study.

Study burden and risks

The risks of participating in the study are negligible. The inhaler used is a specially designed dummy without drug or excipient, so the child will not inhale anything but air during the test. The burden is minimal as the procedures are limited to five registered inhalations only (and the opportunity to practise). Furthermore, the test will be performed under the least burdensome and stressful conditions, i.e. at the children*s own primary school, which is a known and safe environment for the children, and during school hours. Per child, the test is limited to one test moment that lasts maximally 30 minutes. This observational study has no specific benefits for the participating (healthy) children. Only when performed in this population, group related information on the intellectual and inspiratory capacities of school children can be obtained.

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

• Registered at the primary school
• Informed consent of parent(s)/guardian(s)
• Assent of the child

Exclusion criteria

No exclusion criteria are formulated. In principle, all children registered at the primary school are eligible to participate.

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):	25-06-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL39283.042.12

Study results

Date completed:	06-07-2012
Actual enrolment:	104