Investigation of the applicability of dry powder inhalation in children with cystic fibrosis

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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-OMON40571

Source
ToetsingOnline

Brief title
Dry powder inhalation in children with CF

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 achieve a proper inhalation manoeuvre with the test inhaler, which is reflected in the pressure drop they create over the inhaler upon inhalation.

Secondary outcome

From the (duration of the) pressure drop, various inspiratory parameters will be calculated per airflow resistance. The incidence of obstructions in the oral cavity upon inhalation will be expressed as percentage of the total number of observations.

Study description

Background summary

The department of Pharmaceutical Technology and Biopharmacy works on improving drug delivery to the lungs, in particular for severe diseases like cystic fibrosis (CF). The complications associated with CF occur already at a young age, of which ever-recurring lung infections are the main cause for the patient*s early death. Early, effective treatment of these infections might prevent or postpone the transition into a chronic infection. The current treatment of lung infections in CF with nebulised antibiotics has several disadvantages, like a low lung deposition efficacy and a long administration time. Therapy with a dry powder inhaler (DPI) has the potential to be superior over nebulisation, but limited literature is available on DPI applicability in children. We conducted a study in healthy school children to determine their cognitive and inspiratory capacities concerning dry powder inhalation by use of a test inhaler (ChildDPI-1, METc no. 2011-281). The present follow-up study will investigate DPI applicability in children with CF by a comparable approach, in which we narrowed down the number of airflow resistances and mouthpiece designs to those that appeared most suitable for and most favoured

by healthy children.

Study objective

The main objective is to determine whether children with CF are able to achieve an inhalation manoeuvre as required for aerosol generation and transport into the peripheral airways with the test inhaler. The secondary objectives are to determine which of three resistance modes, which of two mouthpiece designs are most suitable for children with CF, and whether an exacerbation influences the child*s ability to perform a proper inhalation manoeuvre.

Study design

Non-therapeutic, observational study.

Study burden and risks

The risks of participating in the study are negligible. The inhaler used is a dummy without drug or excipient, so the child inhales nothing but air during the test. The burden is minimal as the procedures are limited to the performance of six inhalations (and practice), which will be performed on the day of their routine check-up at the clinic. There are one or two test moments per child that last maximally 30 minutes at a time. Participation has no direct benefit for the children. Only when performed in this population, group related information on the cognitive and inspiratory capacities of children with CF can be obtained.

Contacts

Public
Rijksuniversiteit Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL
Scientific
Rijksuniversiteit Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- A physician*s diagnosis of CF
- 4 to 14 years of age
- Informed consent from the parent(s)/guardian(s)
- Assent from the child (informed consent when >=12 years of age)

Exclusion criteria

No exclusion criteria are formulated.

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):	22-05-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2014
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	NL47385.042.14