Home spirometry to predict pulmonary exacerbations in CF: fact or fiction?

Published: 28-02-2008
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To determine if home spirometry (FEV1) predicts pulmonary exacerbation of CF before symptoms appear.

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

Summary

ID

NL-OMON31702

Source
ToetsingOnline

Brief title
Home spirometry in CF

Condition

- Respiratory tract infections

Synonym
Cystic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Eigen geld vakgroep kinderlongziekten

Intervention

Keyword: children, Cystic fibrosis, exacerbation, home spirometry

Outcome measures

Primary outcome

Analysis of home measured FEV1 before, during and after a antibiotic treatment (excacerbation). A decrease of 10% or more of the FEV1 compared to the personal best on 3 days in a row, or a decrease wich is slowl progressive in 7 days, and results in a decrease of 10% or more in FEV1 is defined as a clinical relavent decrease in pulmonary function.

Secondary outcome

not applicable

Study description

Background summary

Cystic Fibrosis is a chronic disease with destruction of lung in time due to mucus plugging, and recurrent bacterial infections. One of the main goals in therapy in CF is to treat pulmonary infections. These infections are diagnosed on complaints and pulmonary function especially the forced expiratory volume in the first second(FEV1). In this study we want to research if home measurement of FEV1 is a reliable early indicator of pulmonary infections in CF.

Study objective

To determine if home spirometry (FEV1) predicts pulmonary exacerbation of CF before symptoms appear.

Study design

longitudinal observational study

Study burden and risks

The patients have to perform a FEV1 once a day, every day, during 1 year. And they have to point out their state of CF-well being in a visual analogue scale.

There are no risks in using a home spirometry device.

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

Cystic Fibrosis
Able to perform spirometry
age 4-18 years old

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	28-02-2008
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	NL21161.042.08