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

Published: 28-02-2008 Last updated: 07-05-2024

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

1 - Home spirometry to predict pulmonary exacerbations in CF: fact or fiction? 6-05-2025

#### **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**

#### **Public**

Academisch Medisch Centrum

postbus 30001 9700 RB Groningen Nederland **Scientific** 

Academisch Medisch Centrum

postbus 30001 9700 RB Groningen Nederland

## **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**

# 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