Telemonitoring of pulmonary function in patients with Cystic Fibrosis

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To assess whether internet-based telemonitoring of pulmonary function at home can prevent severe pulmonary exacerbations and lead to a reduction of hospital admission in patients with CF

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28124

Bron
Nationaal Trial Register

Verkorte titel
tele 1

Aandoening

Cystic Fibrosis
Cystische Fibrose

Ondersteuning

Primaire sponsor: Erasmus Mc
department of pulmonary diseases
Erasmus MC
‘s Gravendijkwal 230
Rotterdam
The Netherlands
Overige ondersteuning: Still negotiating

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Number of severe exacerbations.
A severe exacerbation is defined as an exacerbation which requires treatment with intravenous antibiotic therapy, at the discretion of the treating lung physician.

- Number of moderate exacerbations.
A moderate exacerbation is defined as exacerbation which allows treatment with oral antibiotic therapy, at the discretion of the treating lung physician.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

The pathophysiology of CF is characterized by the development of mucus plugging in the airways and recurring lung infection. This leads to progressive worsening of the lung function, resulting in damage to the airways and, ultimately, death. Pulmonary disease in patients with CF is characterized by an abnormal composition of the epithelial lining fluid. As a result, patients develop chronic airway infection and inflammation that starts early in life.
During CF exacerbations, there is more sputum and more inflammation. During these episodes the condition of the patients deteriorates. These episodes are characterized by increased cough, difficulty to expectorate sputum, loss of appetite and fatigue, weight loss, decreased quality of life and decreases in spirometric parameters. Treatment normally consists of a temporarily treatment with specific antibiotic therapy based on a recent sputum culture. When the exacerbation is moderate, antibiotic treatment can be given at home (orally or intravenous), but when the exacerbation is severe, the patient must be admitted to the hospital for intravenous antibiotic treatment. Hospital admission has a great impact on the quality of life and well-being of a patient, because patients have to stay for about 3 weeks in a single room without contact with other patients to prevent cross-infection. Moreover, it is associated with high health care costs.

Pulmonary function is an important measure of disease severity and prognosis in CF, and is routinely measured at each clinic visit every three months with spirometry. It has been suggested that pulmonary function usually deteriorates earlier than symptoms are perceived and reported. Recently, a new technology, internet based telemonitoring, has been developed to monitor pulmonary function at home by means of spirometry self-testing. Telemonitoring can attribute to an early diagnosis of an exacerbation and early treatment hereof. Severe exacerbations may be prevented so that the patient can remain at home as long as possible. This device has been shown useful in monitoring and treatment of patients with asthma and COPD, but its effectiveness has not yet been shown in CF patients.

Objective(s):

To assess whether internet-based telemonitoring of pulmonary function at home can prevent severe pulmonary exacerbations and lead to a reduction of hospital admission in patients with CF.

Study design:

A pre-experimental prospective cohort study

Number of patients:

28

Inclusion criteria:

- Age 18 years or older

- Male or female

- Diagnosis of CF confirmed by sweat-test and/or DNA analysis and/or electrophysiology testing

- Stable disease

- Signed written informed consent.

Exclusion criteria:

- Placing on the High Urgency waiting list for lung transplantation

Intervention:

- Internet-based telemonitoring of pulmonary function by means of spirometry self-testing

- Lung function measurement will be performed with a handheld spirometer (Viasys healthcare, AM-2 Plus Pro).

- Each participating patient will be asked to fill in a symptom score (electronic) and then

perform spirometry.

- The data will be transmitted to the hospital (by modem).

- When there is an increase in symptoms or reduction in individual spirometry values (FEV1, FVC), a CF nurse will contact the patient by phone. If treatment is indicated, it will be started immediately.

- In case of non-compliance an alert will be given. The patient will be contacted by phone and asked to perform spirometry and assessment of symptoms.

Primary endpoints:

- Number of severe exacerbations.
A severe exacerbation is defined as an exacerbation which requires treatment with intravenous antibiotic therapy, at the discretion of the treating lung physician.

- Number of moderate exacerbations.
A moderate exacerbation is defined as exacerbation which allows treatment with oral antibiotic therapy, at the discretion of the treating lung physician.

Secondary endpoints:

- Quality of life, assessed with EQ-5D and Cystic Fibrosis Questionnairy (CFQ).

- Number and route (oral or intravenous) of antibiotic treatment

- Number of emergency room visits in case of suspicion of pulmonary exacerbation

- Compliance/adherence with self-testing spirometry assessed with a compliance survey

Doel van het onderzoek

To assess whether internet-based telemonitoring of pulmonary function at home can prevent severe pulmonary exacerbations and lead to a reduction of hospital admission in patients with CF

Onderzoeksopzet

- Patients will be asked to perform spirometry (at a fixed time point, once a week) and transmit an electronic symptom diary and the spirometry results to the clinic

- Quality of Life: the questionnaires are completed at baseline, month 6 and at end of study

Onderzoeksproduct en/of interventie

- Internet-based telemonitoring of pulmonary function by means of spirometry self-testing

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 years or older

2. Diagnosis of CF confirmed by sweat-test and/or DNA analysis and/or electrophysiology testing

- Stable disease

- Signed written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Placing on the High Urgency waiting list for lung transplantation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	28
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31622
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1227
NTR-old	NTR1272
CCMO	NL20185.078.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31622

Resultaten

Samenvatting resultaten
N/A