Prevention of CF exacerbation in childhood (PREVEC-study): early recognition by non-invasive biomarkers in exhaled breath (condensate) and early antibiotic treatment

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To assess the efficacy of an intervention directed towards prevention of clinical CF exacerbations by means of early recognition and early antibiotic treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON38104

Source
ToetsingOnline

Brief title
Prevention of CF exacerbations in childhood (PREVEC-study)

Condition

- Bronchial disorders (excl neoplasms)

Synonym
CF, cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Chiesi Pharmaceutics B.V, ,Nederlandse Cystic Fibrosis Stichting

Intervention

Keyword: CF, children, cystic fibrosis, exhaled breath condensate, inflammation, volatile organic compounds

Outcome measures

Primary outcome

Primary outcome measures: exacerbations (the time until the first exacerbation,

the number of exacerbations) and lung function (forced expiratory volume in one

second, FEV1 % predicted value).

Secondary outcome

Secondary outcome measures are respiratory symptoms, quality of life (CFQ),

antibiotic resistance of cultured sputum bacteria, CT imaging, antibiotic

courses, failures of exacerbation prediction, and hospital admission.

Study description

Background summary

Pulmonary exacerbations of CF are an important cause for the experienced disability of patients, respiratory symptoms, and decreases in lung function, which require antibiotic therapy at home or in the hospital. Therefore, prevention of exacerbations in CF is important. In an earlier prospective study during one year, we have demonstrated that non-invasive inflammatory markers in exhaled breath (condensate) are able to predict clinical CF exacerbation before they are clinically manifest.

Study objective

To assess the efficacy of an intervention directed towards prevention of

clinical CF exacerbations by means of early recognition and early antibiotic treatment.

Study design

RCT during two years

Intervention

2-monthly assessments of non-invasive inflammatory markers in exhaled air and exhaled breath condensate to guide antibiotic treatment (active intervention group) compared to usual care.

Study burden and risks

The burden for children with CF in this two-year lasting RCT is limited to 2-monthly assessments of symptoms, physical examination, quality of life (questionnaires), lung function (maximal expiratory flow-volume curves), and non-invasive collection of exhaled breath (condensate). Moreover, home monitoring by means of the AM2-monitor with 3-weekly assessments of symptoms and lung function will be performed in order to detect an exacerbation reliably. These measurements are non-invasive, completely safe and without any health risks. As CF children in the Netherlands come to the outpatient clinic every 3 months, the extra burden because of this study is limited.

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

Children with CF aged 5-18 years will be recruited.
CF disease is defined as the combination of: 1) characteristic clinical features (persistent pulmonary symptoms, meconium ileus, failure to thrive, steatorrhoe); 2) and/or abnormal sweat test (chloride > 60mM); 3) and/or two CF mutations.

Exclusion criteria

Exclusion criteria are: 1) cardiac abnormalities; 2) mental retardation; 3) no technical satisfactory performance of measurements; 4) on the waiting list for lung transplantation; 5) non-compliance with the home-assessments; 6) patients with Burkholderia Cepacia; 7) participation in another intervention trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	22-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-06-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-08-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01241890
CCMO	NL34224.068.10

Study results

Date completed:	01-09-2013
Actual enrolment:	49