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# Analysis of the Pseudomonas aeruginosa biofilm in the respiratory samples of cystic fibrosis patients

**Submission date**
21/12/2012

**Recruitment status**
No longer recruiting

**Registration date**
06/02/2013

**Overall study status**
Completed

**Last Edited**
22/03/2018

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is an inherited disease that affects the internal organs, mainly the lungs and digestive system, by forming thick mucus plugs. Chronic pulmonary infections by the bacteria Pseudomonas aeruginosa (P. aeruginosa) are the main cause of mortality in CF patients. The specific biofilm mode of growth of P. aeruginosa in the CF-mucus enables this bacterium to escape the host immune system and currently available anti-microbial therapies and airway clearance techniques. Standard airway clearance techniques consist of autogenic drainage. A new technique is intrapulmonary percussive ventilation (IPV), in which chest physical therapy is administered to the airways by a pneumatic device that delivers percussive bursts into the lungs in certain frequencies (100-300, up to 900bpm). Research at the Belgian Nuclear Research Centre (SCKCEN) showed that cultivation in a low fluid shear environment induced a P. aeruginosa biofilm phenotype similar to that in CF, while cultivation in a higher fluid shear did not support development of this CF phenotype. The main goal of this study is to investigate the influence of fluid shear on the P. aeruginosa biofilm in CF patients using IPV.

Who can participate?
Patients with CF (age greater than 6 years) who are hospitalised 3 to 4 times a year during 10 days or routine IV antibiotic treatment. Patients must be able to produce sputum. We will compare the patients who are infected with Pseudomonas aeruginosa (patient group), to those who are not infected (control group).

What does the study involve?
For each study participant, three different physiotherapy regimens will be tested during three different hospitalisation periods: autogenous drainage, IPV low frequency (200 bpm) and IPV high frequency (400 bpm). In the patient group we will analyse sputum samples for P. aeruginosa characteristics before and after the different physiotherapy regimens. This study will be performed blind which means that the researcher who analyses the samples in the lab will not be informed of the therapeutic group to which the patient belongs.

What are the possible benefits and risks of participating?
All treatments adopted during this study are routinely used by CF patients and have been proven to be safe. Consequently, this study does not involve any risk for the patient. New insights gained from this study will improve the understanding of bacterial behaviour following exposure to high shear treatment in vivo and will be applied to a purposive adaptation of the current treatment of cystic fibrosis patients.

Where is the study run from?
The CF reference centre at the University Hospital in Brussels (UZ Brussel), Belgium

When is study starting and how long is it expected to run for?
Patient recruitment started in January 2012 and the study will run until January 2014

Who is funding the study?
Belgian Cystic Fibrosis Association (BCFA) (Belgium)

Who is the main contact?
Dr J. Willekens
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Julie Willekens

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# Additional identifiers

### Protocol serial number
BUN14320095387

# Study information

### Scientific Title
Effect of intrapulmonary percussive ventilation on Pseudomonas aeruginosa biofilm formation and virulence

### Study objectives
Assuming that the lung mucus in cystic fibrosis (CF) patients is characterized by low fluid shear (as the main shear-causing factor, mucociliary clearance, is absent), we want to investigate the

impact of increased fluid shear on P. aeruginosa growth features and virulence in vivo. For this purpose, we want to use intrapulmonary percussive ventilation (IPV) as this presumably increases fluid shear in the lungs.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethics Committee UZ Brussel, 01/12/2011, ref: 2009/004

### Study design
Randomised controlled single-blind cross-over trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Cystic fibrosis / Pseudomonas aeruginosa biofilm / Intrapulmonary Percussive Ventilation (IPV)

### Interventions
Three different physiotherapy regimens (each patient will have all 3 regimens with a 3-month interval):
1. Autogenous drainage
2. IPV low frequency (200 bpm)
3. IPV high frequency (400 bpm)

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Analysis of P. aeruginosa abundance, physiology, virulence factors and gene expression on day 1, day 4 and day 10 of each hospitalisation

### Key secondary outcome(s))
Lung function values [Forced expiratory volume in the first one second (FEV1) and forced vital capacity (FVC)] on day 1 and day 10 of each hospitalisation

### Completion date
01/01/2014

## Eligibility

### Key inclusion criteria
1. CF patients (diagnosis confirmed by sweat test)
2. Age greater than 6 years, upper age limit 60 years
3. Hospitalisation 3 to 4 times a year for routine intravenous (IV) antibiotic treatment
4. Clinically stable at time of study entry

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Mixed

**Sex**
All

**Key exclusion criteria**
1. Lung transplantation
2. Massive hemoptysis
3. Pneumothorax
4. Pregnancy
5. Non-invasive and invasive ventilation

**Date of first enrolment**
01/01/2012

**Date of final enrolment**
01/01/2014

# Locations

**Countries of recruitment**
Belgium

**Study participating centre**
**Laarbeeklaan 101**
Jette
Belgium
1090

# Sponsor information

**Organisation**
Belgian Cystic Fibrosis Association (BCFA) (Belgium)

# Funder(s)

**Funder type**
Charity

**Funder Name**
Belgian Cystic Fibrosis Association (BCFA) (Belgium)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2018 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |