ISRCTN75391385 https://doi.org/10.1186/ISRCTN75391385

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Analysis of P. aeruginosa abundance, physiology, virulence factors and gene expression on day 1, day 4 and day 10 of each hospitalisation

Secondary outcome measures
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

Overall study start date
01/01/2012

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

Age group
Mixed

Sex
Both

Target number of participants
10

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)

Sponsor details
Avenue J. Borlé 12
Brussel
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1160

Sponsor type
Charity

Website
http://www.muco.be

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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