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Methicillin-resistant Staphylococcus aureus (MRSA) eradication in Cystic Fibrosis patients: influence on lung function values

Submission date
22/01/2013

Recruitment status
No longer recruiting

Registration date
03/04/2013

Overall study status
Completed

Last Edited
13/08/2020

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. Respiratory infections are an important cause of morbidity in CF patients. With increasing survival due to improvements of care, an increased frequency of pulmonary infections with new and resistant pathogens has been identified. In particular, the prevalence of methicillin-resistant Staphyylococcus aureus (MRSA) in respiratory cultures of CF patients has increased over the past decade. Because MRSA infection can have a negative impact on lung function values, antibiotic treatment is initiated when MRSA is found and the treatment removes ('eradicates') MRSA from the respiratory tract.
This study aims to investigate the influence of MRSA eradication on lung function values.

Who can participate?
Patients with CF, aged over 6 years old and with MRSA found in the respiratory culture

What does the study involve?
Patients will receive a combination of 2 antibiotics, during 6 months. Respiratory samples will be analysed after 3 and 6 months, and at 3 and 6 months after eradication was completed. Lung function will be measured before start of eradication, at 3 and 6 months after start of eradication, and at 3 and 6 months after completion of eradication.

What are the possible benefits and risks of participating?
The treatment used in this study has been studied before and has been proven to be safe and effective. Possible side effects are gastro-intestinal complaints.
New insights gained from this study will improve the understanding of the influence of MRSA infection on lung function.

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

When is the study starting and how long is it expected to run for?
Patient recruitment started in June 2012 and the study will run until June 2015.

Who is funding the study?
Universitair Ziekenhuis Brussel, Brussels, Belgium

Who is the main contact?
Dr. Eef Vanderhelst
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
B.U.N.143201213745

Study information

Scientific Title
MRSA eradication in Cystic Fibrosis: treatment protocol and impact on lung function decline and lung clearance index

Study objectives
Chronic methicillin-resistant Staphyylococcus aureus (MRSA) infection is associated with a faster lung function decline in cystic fibrosis (CF) patients. We want to investigate the influence of MRSA eradication on lung function decline and lung clearance index. In addition, we want to evaluate the efficiency of the used antibiotics scheme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee UZ Brussel, 29 March 2012, Reference number: 2012/079

Primary study design

Interventional

Study design
Single-centre prospective open label study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cystic fibrosis - MRSA infection

Interventions
Treatment of MRSA infection:
Decolonisation (nasal Mupirocin and Chlorhexidin soap and throat spray): every day during 5 days

Peroral antibiotics (Fusidic acid and Rifampicin): every day during 6 months

Measurement of lung function (including Lung Clearance Index, LCI) and analysis of respiratory samples at different time points: D0, after 3 and 6 months, and 3 and 6 months after stop of eradication.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mupirocin, Chlorhexidin, Fusidic acid, Rifampicin

Primary outcome(s)
Eradication of MRSA from the respiratory samples during and after completion of eradication

Key secondary outcome(s)
1. Lung function values (including LCI)
2. Clinical status

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Cystic fibrosis (CF) patients (diagnosis confirmed by sweat test)
2. Age greater than 6 years - 60 years, either sex
3. Newly acquired MRSA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Lung transplantation
2. Pregnancy

Date of first enrolment
01/06/2012

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Belgium

Study participating centre
Universitair Ziekenhuis Brussel
Brussels
Belgium
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Sponsor information

Organisation
University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium)

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (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	01/12/2013	13/08/2020	Yes	No