

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/08/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 *Staphylococcus 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
eef.vanderhelst@uzbrussel.be

Contact information

Type(s)
Scientific

Contact name
Dr Eef Vanderhelst

Contact details
Universitair Ziekenhuis Brussel
Laarbeeklaan 101
Brussels
Belgium
1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Staphylococcus 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

Study design

Single-centre prospective open label study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

Eradication of MRSA from the respiratory samples during and after completion of eradication

Secondary outcome measures

1. Lung function values (including LCI)
2. Clinical status

Overall study start date

01/06/2012

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

Age group

Adult

Sex

Both

Target number of participants

25

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
1090

Sponsor information

Organisation

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

Sponsor details

Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor type

Hospital/treatment centre

Website

<http://www.uzbrussel.be>

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

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	01/12/2013	13/08/2020	Yes	No