Monocytes in TiMaSCAN for monitoring respiratory infections in CF

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25786

Source
Nationaal Trial Register

Brief title
MONITOR CF

Health condition

Cystic Fibosis

Sponsors and support

Primary sponsor: N.a.
Source(s) of monetary or material Support: Sophia Foundation

Intervention

Outcome measures

Primary outcome

The percentage of concordance of positive TiMaSCAN result for a CF-specific pathogen with result of sputum or BAL cultures

Secondary outcome

- The percentage of disconcordance of positive TiMaSCAN result for a CF specific pathogen with the result of sputum or cough swab cultures.
- Correlation pathogen-positive TiMas with lung function
- Correlation pathogen-positive TiMas with mean change in CFRSD/CRISS score and CFQ-R
- Correlation number of pathogen-positive TiMas at end of treatment with time to next exacerbation, with either oral or iv treatment (follow up of maximum one year)

Study description

Background summary

Proper diagnosis and treatment of lung infections in children with Cystic Fibrosis (CF) is important because damage to the lungs from infections reduces life expectancy. The choice of treatment (antibiotics) and duration thereof is now based on symptoms, lung function and suboptimal lab results. A new rapid test that can detect infections, developed at the Sophia Children's Hospital, may contribute to better diagnostics. In this project we would like to apply this test in children with CF and investigate whether this contributes to better detection of infections in the lungs. This can improve treatment.

Study objective

Our hypothesis is that TiMaSCAN results will correlate with airway cultures and that the amount of pathogen-positive TiMas will decrease over the course of antibiotic treatment.

Study design

Day of admission:
- Baseline characteristics (such as age, gender, mutation, growth, antibiotic and other medication are collected (n=20))
- If applicable, from some patients BALF will be obtained by bronchoscopy

Start of intravenous antibiotics treatment (day 0)
- Spirometry
- sputum for culture
- EDTA blood samples for TiMaSCAN
- CFRSD/CRISS questionnaire

After one week of treatment (day 7):
- Spirometry
- sputum for culture
- EDTA blood samples for TiMaSCAN
- CFRSD/CRISS questionnaire

End of treatment (day 14)

- Spirometry
- sputum for culture
- EDTA blood samples for TiMaSCAN
- CFRSD/CRISS questionnaire

Usually an iv antibiotic course is 2 weeks, if it is 3 weeks, then there will be an extra study time point after 2 weeks

Contacts

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Eligibility criteria

Inclusion criteria

• Diagnosed with CF, either by abnormal sweat test and/or confirmed with 2 mutations found by genetic analysis, either from heel-prick screening or diagnosed later in life;
• Aged 5 – 18 years at time of hospitalization;
• Able to perform lung function test;
• Having an indication to receive intravenous antibiotic treatment because of a pulmonary exacerbation
• Authorized by a written informed consent from parents (and patient, if aged > 12) to collect a vial of EDTA blood from i.v. canula, to undergo a sputum induction (if sputum collection is not possible, a cough swab is collected) and to assess lung function, and permission to use excess biomaterials and coded clinical data for research.

Parents may choose to opt in or out for separate parts of the study.

Exclusion criteria

• Diagnosed with allergic bronchopulmonary Aspergillosis
• Use of prednisone
• Antibiotic iv treatment has already been started more than 12 hours before collection of first blood and/or sputum cultures
• Use of inhaled antibiotics during antibiotic iv course.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-08-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 51190
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9423
CCMO	NL77646.078.21
OMON	NL-OMON51190

Study results