Monocytes in TiMaSCAN for monitoring respiratory infections in CF

Gepubliceerd: 22-04-2021 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25786

Bron
Nationaal Trial Register

Verkorte titel
MONITOR CF

Aandoening

Cystic Fibosis

Ondersteuning

Primaire sponsor: N.a.
Overige ondersteuning: Sophia Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

Erasmus MC
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010-7044654

Wetenschappelijk

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Wendy Unger

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-08-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51190
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten