



Title:

PRospective Evaluation of Nontuberculous Mycobacteria Disease in CysTic Fibrosis: The design of the PREDICT study

Lay Title:

Making the diagnosis of nontuberculous mycobacteria (NTM) lung disease standard with the PREDICT study

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What was your research question?

How can we make the diagnosis of NTM disease in CF uniform? What are the best predictors of NTM lung disease? Can we discover new biomarkers that detect NTM lung disease?

Why is this important?

People with CF may grow NTM from their sputum, but this does not necessarily mean they have NTM lung disease that requires treatment. The decision to diagnose and treat NTM lung

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disease depends on faster clinical decline than expected in CF. The PREDICT study aims to identify the important signs, symptoms and markers to quickly and accurately evaluate and diagnose NTM lung disease.

What did you do?

We designed a study protocol to follow people with CF (older than age 6) with a recent positive NTM culture. The protocol observes and records individual changes in their clinical outcomes overtime and emphasizes optimization of all aspects of CF care. We also are collecting samples like blood and urine to explore new markers of NTM disease. The focus is the diagnosis of NTM lung disease, in order to identify people who may benefit from antibiotic treatment of the infection. The study is ongoing at many Centers in the United States.

What did you find?

We are not reporting results, but rather explaining how we have designed the PREDICT study. This report is the foundation for a series of publications that will report the findings from this study.

What does this mean and reasons for caution?

This approach to diagnosing and starting treatment for NTM lung disease is based on consensus guidelines, but has not yet been proven. It is possible that in the future, methods that are more accurate will be discovered to identify whom to treat for this infection.

What's next?

We are continuing to enrol and follow patients in this study, and analyse samples for biomarkers. Results will be available on ClinicalTrials.gov, conference presentations and peer-review publications.

Appendix: Investigators of the Cystic Fibrosis NTM Consortium

G. Marty Solomon, MD, University of Alabama Birmingham, Alabama, United States Thomas G. Keens, MD, Children's Hospital of Los Angeles Los Angeles, California, United States

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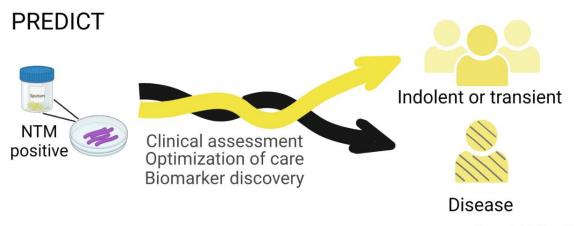
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