PredictTB

Using Biomarkers to Predict TB Treatment Duration

FACT SHEET

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Acronym
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Full Title
Using Biomarkers to Predict TB Treatment Duration

Funding
In total, the Predict-TB project will receive over 20 million EUR funding from the EDCTP, the Bill & Melinda Gates Foundation through the Foundation for the National Institutes of Health and through Grand Challenges China with the Natural Science Foundation China (NSFC), the National Institutes of Health, the NIH's International Collaborations in Infectious Disease Research (ICIDR) Program in collaboration with the Consortium for TB Biomarkers and the Regional Prospective Observational Research in Tuberculosis in the Republic of South Africa (RePORT South Africa).

Duration
66 months (01/02/2017 - 31/07/2022)

ABSTRACT
Current treatments for TB use a one-size-fits-all approach and usually lasts for at least six months. Shortening the standard treatment of TB could help reduce drug resistance and disease burden in developing countries.

Previous attempts to shorten treatment duration, usually to four months, have been unsuccessful when compared with six-month treatments. While six-month courses cure 95% of patients, shorter courses only cure 80-85%. However, this still means that most patients are cured after four months. The problem is that we currently cannot know beforehand which patients belong to that group. If clinicians were able to identify the patients who only require four-month therapy before starting treatment, treatment duration could be reduced in most patients, even with present drugs.

While current biomarkers to predict treatment outcome are insufficient, previous studies have provided important clues indicating that the extent of disease and bacterial burden are important contributors to poor treatment outcome.

PredictTB will look at data from PET/CT scans, assays, and cultures from 620 clinical trial patients in South Africa and China to test for the sustained presence of host response and Mtb bacteria and to determine which patients are eligible for shortened treatment. Those who meet early treatment completion criteria will be randomised at month four either to continue therapy for the standard duration or to complete early at month four, whereas those who fail to meet early completion criteria will continue on the standard regimen. Patients enrolled in the trial will be followed up until 18 months after treatment start.

Hypothesis
A combination of microbiological and radiographic biomarkers will identify TB patients who are cured with four months of conventional therapy.

Primary Objective
To demonstrate during the 18-month check-up that for subjects classified as low risk by PET/CT and bacterial load markers, standard treatment stopped at month four is no less effective than standard treatment stopped at month six.

Secondary Objectives
1. To evaluate the association of demographic, radiographic, bacterial load, microbiologic, and immunologic markers for predicting poor treatment outcome in the following cohorts:
   a. A pooling of high and low risk arms receiving the same duration of therapy to evaluate the risk criteria.
   b. A comparison between low risk arms with shortened and standard treatment to evaluate any covariates which predict greater rates of poor outcomes under treatment shortening.
2. To store biological samples for future biomarker research.
3. To develop a point-of-care lateral flow device to measure immunological markers as additional or replacement stopping criteria.

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- The Foundation for the National Institutes of Health, United States
- Catalysis Foundation for Health, United States

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- Imperial College London, United Kingdom
- University of Zurich, Switzerland
- Fudan University, China
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