PITBUL Protocol

Title of the study

"Point-of-care Implementation of TB testing with Ultra-Fast Local heating PCR (PITBUL)".

Rationale and impact of the study

The basic principle of the tuberculosis control strategy is the timely diagnosis and effective treatment of all cases of active tuberculosis (TB), with particular regard to infectious forms and cases of multidrug-resistant TB (MDR TB).

The main requirement for a timely diagnosis of MDR TB is to improve access to rapid molecular resistance tests, as well as to ensure treatment according to WHO guidelines in reference centers and minimizing the number of subjects lost to follow-up.

Point-of-care testing (POCT) is a way to perform medical analysis outside the reference laboratory near the patient's care site. This increases the likelihood that the patient, the doctor, and the care team receive the results more quickly and therefore that diagnostic and therapeutic decisions are timely.

This new fully automated diagnostic approach allows the treatment of TB, and in particular of MDR TB, to considerably reduce the time (at a few hours) for the initiation of an appropriate therapy and therefore the patient's contagiousness, preventing the onset of drug resistance resulting from ineffective treatment.

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The project will have a total duration of 30 months starting from 1 December 2017.

Objective of the study

The main objective of the study is to develop evaluate and validate a new molecular test to be performed at patient's bed, called "Ultra-fast Local Heating PCR (ultra-rapid PCR molecular test)", for the rapid diagnosis of active TB and for the characterization of possible mutations of M. tuberculosis associated with resistance to antituberculotic drugs.

In the initial steps of the projects the objective is to develop the several components of the test: processing of the biological sample, inactivation and lysis of mycobacterium, DNA extraction, detection of molecular markers for TB diagnosis and detection of mutations correlated to drug-resistance.

Subsequently the different components of the test will be integrated within a single automated system, ideal for POCT use.

The evaluation of the efficacy of the test (sensitivity, specificity, predictive values, time and costs) and the clinical validation performed on clinical samples from patients with a suspect of active TB, will be carried out during the final phase of the project, as described in further detail in the methodology section.