

US finds temperature-stable TB vaccine safe, with prompt immune response

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A single-vial presentation of a thermostable vaccine would have clear advantages in ease of storage, transport and administration



A clinical trial testing a freeze-dried, temperature-stable experimental tuberculosis (TB) vaccine in healthy adults found that it was safe and stimulated both antibodies and responses from the cellular arm of the immune system.

The Phase 1 trial was supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health in the US. A non-temperature stable form of the candidate previously had been tested in several clinical trials. However, this was the first clinical trial of any subunit TB vaccine candidate in a temperature-stable (thermostable) form.

The investigators note some limitations in this small trial. For example, no established correlates of protection define what immune responses are required for vaccine-induced protection from TB disease. Therefore, it is not possible to say whether the enhanced immune responses seen in the thermostable vaccine formulation would translate to improved protective vaccine efficacy.

Nevertheless, they conclude, results of this trial demonstrate “a proof-of-concept that adjuvant-containing vaccines can be formulated in a freeze-dried single-vial presentation without detrimentally impacting clinical immunogenicity or safety characteristics.”