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# NCT04556981 Safety and Immunogenicity of M72/AS01E in Participants With Well-controlled HIV (MESA-TB)

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MESA-TB trial NCT04556981

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Protocol Title: A randomized, placebo-controlled, observer-blind, phase 2 study to evaluate safety and immunogenicity of the investigational M72/AS01E Mycobacterium tuberculosis (Mtb) vaccine in virally suppressed, antiretroviral-treated participants with human immunodeficiency virus (HIV)

Short Title: Safety and immunogenicity of a TB vaccine M72/AS01E in participants with well controlled HIV

Rationale:

Published phase 1 and 2 randomized, controlled trials evaluating M72/AS01E vaccination in individuals with HIV who were receiving antiretroviral therapy (ART) show that a 2-dose schedule of the vaccine given one month apart is well-tolerated and immunogenic in this population. This current study intends to confirm that the vaccine is safe, well-tolerated, and immunogenic in a larger population of people with virally suppressed HIV infection in a tuberculosis (TB) endemic region.

[NCT04556981 Protocol  
Version 3.0\\_Redacted.pdf](#)

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<https://clinicaltrials.gov/ct2/show/NCT04556981>

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M72/AS01E investigational tuberculosis vaccine, Phase 2, clinical trial

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