A phase I trial evaluating the safety and immunogenicity of a candidate tuberculosis vaccination regimen, ChAdOx1 85A prime - MVA85A boost in healthy UK adults

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This phase I trial evaluated the safety and immunogenicity of a candidate tuberculosis vaccination regimen, ChAdOx1 85A prime-MVA85A boost, previously demonstrated to be protective in animal studies, in healthy UK adults.; We enrolled 42 healthy, BCG-vaccinated adults into 4 groups: low dose Starter Group (n = 6; ChAdOx1 85A alone), high dose groups; Group A (n = 12; ChAdOx1 85A), Group B (n = 12; ChAdOx1 85A prime - MVA85A boost) or Group C (n = 12; ChAdOx1 85A - ChAdOx1 85A prime - MVA85A boost). Safety was determined by collection of solicited and unsolicited vaccine-related adverse events (AEs). Immunogenicity was measured by antigen-specific ex-vivo IFN-γ ELISpot, IgG serum ELISA, and antigen-specific intracellular IFN-γ, TNF-α, IL-2 and IL-17.; AEs were mostly mild/moderate, with no Serious Adverse Events. ChAdOx1 85A induced Ag85A-specific ELISpot and intracellular cytokine CD4+ and CD8+ T cell responses, which were not boosted by a second dose, but were boosted with MVA85A. Polyfunctional CD4+ T cells (IFN-γ, TNF-α and IL-2) and IFN-γ+, TNF-α+ CD8+ T cells were induced by ChAdOx1 85A and boosted by MVA85A. ChAdOx1 85A induced serum Ag85A IgG responses which were boosted by MVA85A.; A ChAdOx1 85A prime - MVA85A boost is well tolerated and immunogenic in healthy UK adults.
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