A first-in-human phase 1 trial to evaluate the safety and immunogenicity of the candidate tuberculosis vaccine MVA85A-IMX313, administered to BCG-vaccinated adults

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Author(s) Minhinnick, Alice; Satti, Iman; Harris, Stephanie; Wilkie, Morven; Sheehan, Sharon; Stockdale, Lisa; Manjaly Thomas, Zita-Rose; Lopez-Ramon, Raquel; Poulton, Ian; Lawrie, Alison; Vermaak, Samantha; Le Vert, Alexandre; Del Campo, Judith; Hill, Fergal; Moss, Paul; McShane, Helen
Author(s) at UniBasel Manjaly Thomas, Zita-Rose ;
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There is an urgent need for a new and effective tuberculosis vaccine because BCG does not sufficiently prevent pulmonary disease. IMX313 is a novel carrier protein designed to improve cellular and humoral immunity. MVA85A-IMX313 is a novel vaccine candidate designed to boost immunity primed by bacillus Calmette-Guérin (BCG) that has been immunogenic in pre-clinical studies. This is the first evaluation of IMX313 delivered as MVA85A-IMX313 in humans.; In this phase 1, open-label first-in-human trial, 30 healthy previously BCG-vaccinated adults were enrolled into three treatment groups and vaccinated with low dose MVA85A-IMX313 (group A), standard dose MVA85A-IMX313 (group B), or MVA85A (group C). Volunteers were followed up for 6 months for safety and immunogenicity assessment.; The majority of adverse events were mild and there were no vaccine-related serious AEs. Both MVA85A-IMX313 and MVA85A induced a significant increase in IFN-γ ELISpot responses. There were no significant differences between the Ag85A ELISpot and intracellular cytokine responses between the two study groups B (MVA85A-IMX313) and C (MVA85A) at any time point post-vaccination.; MVA85A-IMX313 was well tolerated and immunogenic. There was no significant difference in the number of vaccine-related, local or systemic adverse reactions between MVA85A and MVA85A-IMX313 groups. The mycobacteria-specific cellular immune responses induced by MVA85A-IMX313 were not significantly different to those detected in the MVA85A group. In light of this encouraging safety data, further work to improve the potency of molecular adjuvants like IMX313 is merited. This trial was registered on clinicatrials.gov ref. NCT01879163.
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