Oral paratyphoid vaccine to begin human trials

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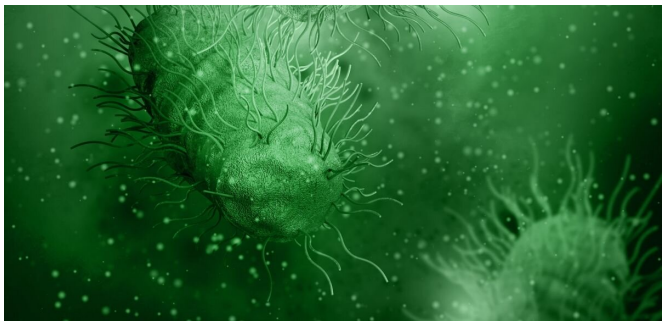

Rendering of the Salmonella bacteria. Credit: sokolova_sv/Shutterstock

The University of Oxford in collaboration with the University of Maryland School of Medicine (UMSoM) has begun recruiting for a Phase I/II trial of a new paratyphoid vaccine in human volunteers in Oxford.

In the first study of its kind, after vaccination volunteers will be "challenged" with paratyphoid to see whether the vaccine can prevent infection.

The Vaccine Against Salmonella Paratyphi (VASP) study will assess the immune response, efficacy and safety of a new vaccine, CVD 1902, against paratyphoid fever (a form of enteric fever similar to typhoid), which is given by mouth as a drink. CVD 1902 was developed by a team of scientists at the Center for Vaccine Development and Global Health (CVD) of the UMSoM. The use of a human challenge model to do this will allow an understanding of the vaccine's effectiveness without having to immunize thousands of people.

A planned sample of up to 76 participants—aged 18 to 55 and in good health—will be randomized to either receive two doses of the new paratyphoid vaccine or a placebo given 14 days apart. All participants will then be challenged with paratyphoid bacteria to see if they are protected against infection.

Following challenge, participants will be monitored closely and treated with antibiotics as soon as they show signs of infection, or after two weeks if they do not show any signs of infection. Results are expected in 2023.

Professor Sir Andrew Pollard, Director of the Oxford Vaccine Group and Chief Investigator of the trial, said:

"Vaccines are urgently needed to prevent the 3.3 million cases of paratyphoid fever that mostly affects school-age children in South and South East Asia. This first human challenge study to evaluate a paratyphoid vaccine will bring us a step closer to reducing the burden of this affliction in the world."

Professor Brian Angus, Director of the Oxford Centre for Clinical Tropical Medicine and Global Health and Principal Investigator of the trial, said:

"Enteric fever is a common infectious disease worldwide spread by drinking contaminated water. Although mainly caused by Salmonella Typhi a quarter of cases are due to another organism Salmonella Paratyphi. A new vaccine has recently been approved for typhoid, but no vaccine currently is licensed for paratyphoid. Due to increasing antibiotic resistance, the need for vaccines against these bacteria are desperately needed."

Dr. Maheshi Ramasamy, Senior Clinical Researcher and Principal Investigator of the trial, said:

"Here in Oxford, we have developed safe, controlled ways of studying malaria, typhoid and COVID-19 infections in volunteers.

"Building on this experience, we will be using a

human model of paratyphoid infection to study the efficacy of a new vaccine against this disease which disproportionately affects low and middle income countries."

Myron (Mike) M. Levine, MD, DTPH, the Simon and Bessie Grollman Distinguished Professor of Medicine and Associate Dean for Global Health, Vaccinology and Infectious Diseases, who led the team at the UMSoM that developed the CVD 1902 vaccine, said:

"An oral vaccine is easy to administer and can stimulate 'local' protective immune responses along the surface of the intestine, as well as systemic immunity. For more than a decade, the CVD and the Oxford Vaccine Group have worked together on projects to find improved ways to prevent typhoid and paratyphoid fevers."

Volunteers interested in enrolling on the study can do so online at https://trials.ovg.ox.ac.uk/trials/vasp

Provided by University of Oxford