MedicalXpress

Oxford Ebola vaccine study moves to next phase

July 15 2015

Oxford University doctors and scientists are performing the second phase of clinical studies of an experimental Ebola vaccine regimen. The study is part of the EBOVAC2 project, a collaborative programme involving the University of Oxford, French Institute of Health and Medical Research (INSERM) as project coordinator, London School of Hygiene & Tropical Medicine (LSHTM), Le Centre Muraz (CM), Inserm Transfert (IT) and the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen).

The EBOVAC2 project is funded under a grant from the European Commission's Innovative Medicine Initiative Ebola+ programme which was launched in response to the Ebola virus disease outbreak. The EBOVAC2 project aims to assess the safety and immunogenicity of a novel prime boost preventative vaccine regimen against Ebola Virus Disease (EVD).

The original development of the prime boost vaccine regimen was accelerated in response to the outbreak of Ebola virus disease in West Africa, which has now claimed more than 11,000 lives. Although the number of confirmed EVD cases has decreased in recent months, new cases of EVD in Liberia, which had been declared Ebola free, highlight that a preventative vaccine may still be needed to control the spread of disease.

The Oxford Vaccine Group, part of the University of Oxford Department of Paediatrics, has started enrolling volunteers for the phase

II study this month, with additional French sites coordinated by Inserm anticipated to start recruitment in August. An additional study is planned to follow in several African countries.

The Phase II study aims to recruit more than 600 healthy adult volunteers in the UK and France.

In the UK, volunteers for the study, aged 18-65 years, are likely to come largely from the Oxfordshire region, and will be asked to make a maximum of 17 visits to the Oxford Vaccine Group site on the city's Churchill hospital site over a period of a year. The Oxford study is supported by the NIHR Oxford Biomedical Research Centre , a partnership between the University of Oxford and Oxford University Hospitals Trust, funded by the National Institute for Health Research.

The vaccine regimen used in the study involves two different components, given a few weeks apart. The first dose is intended to stimulate, or 'prime', an initial immune response. The second dose then is designed to 'boost' the level of the body's immune response further.

Neither vaccine component contains any replicating virus, so it is not possible to be infected with Ebola.

In pre-clinical studies of this vaccine regimen conducted in collaboration with the National Institutes of Health complete protection from death due to Ebola was achieved against the Kikwit variant - which is highly similar to the virus causing the current outbreak in Western Africa. Preliminary results from the first phase of the clinical study, conducted in Oxford and involving 87 volunteers, indicated that the prime-boost vaccine regimen is immunogenic, regardless of the order of vaccine administration, and only provoked temporary reactions normally expected from vaccination.

People interested in volunteering for the clinical study can find out more information at http://www.ebolavaccine.org.uk.

In addition to the Phase II study being conducted in the UK and France, similar studies are also starting in Africa to establish how robust the immune response is to the Ebola vaccine regimen. Given the compressed nature of this development program, the Phase II studies are anticipated to be conducted in parallel with the planned safety and immunogenicity study in Sierra Leone as part of EBOVAC1.

Prof Andrew Pollard, Director of the Oxford Vaccine Group, said: 'The devastating Ebola epidemic in Guinea, Liberia and Sierra Leone has shown how urgently we need a safe and effective vaccine. That goal has brought together manufacturers, public health bodies and research regulators to accelerate these studies of new Ebola vaccines. The results of the first phase, which are due to be published shortly, are encouraging. We are appealing, once again, for volunteers to come forward and help us in the second stage of this vital work.'

The objectives of the EBOVAC2 study are to determine further the vaccine regimen's safety profile and how well it stimulates the immune system to protect against Ebola infection. The team also want to work out the best timing for each of the vaccines. Volunteers will therefore be put on different schedules, where the gap between 'prime' and 'boost' dose will be 28, 56 or 84 days.

The immune responses that the vaccine generates - both antibodies and T cells - will also be measured over a period of one year.

Another team in the Jenner Institute has been studying a different Ebola vaccine (ChAd3 EBOZ) funded by the Wellcome Trust and the Department for International Development and developed with GSK/ US National Institutes of Health. Led by Professor Adrian Hill, preliminary

results from the phase I studies conducted earlier this year have shown that this vaccine has a good safety profile and stimulates an immune response against the Ebola virus. Professor Hill's team has since started on a phase I trial of a boost to this vaccine and recruitment is ongoing.

Provided by Oxford University