NEWS

Trials of Ebola vaccine set to begin in west Africa

Anne Gulland

London

Phase II trials of the two most advanced vaccines against Ebola virus disease will begin in west Africa in the next two to four weeks, the World Health Organization has announced.

Marie-Paule Kieny, assistant director general at WHO, told a press briefing on 9 January that safety trials had been successfully conducted on the two vaccines: cAd3-ZEBOV, a chimpanzee derived adenovirus vaccine developed by GlaxoSmithKline, and rVSV-ZEBOV, now licensed to Merck.

Kieny told journalists that 2014 would be remembered as the year that the Ebola virus challenged humanity, “but 2015 will be remembered as the year that humanity used its best scientific minds and fought back.”

Within the next two to four weeks information on the optimum dose levels will become available, after which the trials will start, firstly in Liberia and then in Sierra Leone and Guinea. It is expected that this fast tracked study will take about six months.

In Liberia a three arm trial will take place to test the vaccines on two groups of around 9000 people each against a control group of the same number. In Sierra Leone just one of the vaccines, yet to be decided, will be tested on around 6000 frontline workers in a stepped wedge (or phased) approach. And in Guinea researchers will use a ring design; that is, when a case of the disease is notified, researchers will vaccinate members of the patient’s community or village.

The Swiss arm of the phase I rVSV-ZEBOV trial was halted at the end of last year when four of 59 volunteers reported mild joint pain in their hands and feet 10 days after injection. Kieny said that this trial had now restarted, as the joint pain was not of “sufficient concern to stop the development of this vaccine.”

Helen Rees, co-chair of WHO’s Ebola vaccine working group, acknowledged that the vaccine might have limited use in the current epidemic. She said, “But in the future we will have this vaccine. This is not going to be the end of Ebola, and we will see sporadic cases that might become more widespread.”

A WHO working group is looking at how to make best use of the vaccine in the three worst affected countries once the trials have ended and at the long term strategy for the vaccine.

Meanwhile, researchers at Oxford University, lead partners of a Wellcome Trust funded study, have announced that a trial of the antiviral brincidofovir has begun at a Médecins Sans Frontières treatment centre in Liberia, with the first patient receiving the drug on 2 January. In this phase II trial, a single arm, open label study with no control group, a two week course of the drug is being given to all patients, except pregnant women, who give consent. The main outcome measure is mortality at two weeks, which will be compared with the previous mortality rate.

Investigators are hoping to test about 100 patients in Liberia, as well as setting up a trial site in Sierra Leone.

Trudie Lang, one of the investigators, said that the trial was put together in four months, instead of the usual 18, with researchers enlisting the help of the US military to get the vaccine, manufactured by North Carolina based Chimerix, to west Africa.

She said that lessons could be learnt in reducing the number of hoops that researchers had to jump through. “There are a lot of processes that can adjust according to the risk and complexity of the trial,” she said. “Often we record every single adverse event, but when we know the drug is relatively safe, and we know what the symptoms of the disease are, it means that writing down every time an Ebola patient vomits would be meaningless statistical noise. Here it is scientifically valid to just capture serious and unexpected events,” she said.

“We have set this up really quickly, but there’s nothing we have compromised on,” she added.

The latest data from WHO show that there have been 20 972 cases of the disease in the three worst affected countries, including 8259 deaths. The incidence of the disease in Sierra Leone, which had seen a large spike in the number of cases, seems to be levelling off.

Cite this as: *BMJ* 2015;350:h165

© BMJ Publishing Group Ltd 2015