

# Clinical trial for experimental Ebola drug publishes results

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Results of the Wellcome Trust funded trial of the experimental anti-Ebola drug TKM-130803 have been published today (April 19) in *PLOS Medicine*. Using a novel approach designed to get rapid indications of a drug's effectiveness, the trial showed that at the dose given the drug did not improve survival compared to historic controls.

TKM-130803 interferes with the production of two essential Ebola virus proteins and has been shown to improve survival when given to monkeys experimentally infected with Ebola virus. Scientists from the University of Oxford and Sierra Leone worked with the humanitarian organisation GOAL Global, the World Health Organisation, and collaborators from a number of other institutions to test whether TKM-130803 could improve survival in adults with Ebola infection.

The researchers used a new approach to generate early evidence of effectiveness or ineffectiveness. This method can be used as a tool to screen potential therapies and determine the need for further studies (including randomised controlled trials) during an epidemic. The approach meant that the study was quickly able to reach a pre-defined point to stop the trial.

The study took place at the GOAL Ebola Treatment Centre in Port Loko, Sierra Leone between 11 March and 15 June 2015. Patients with laboratory-confirmed Ebola who volunteered to participate in the trial were given a once daily infusion of TKM-130803 for up to seven days. After 14 patients had received TKM-130803 the pre-specified statistical

endpoint was reached and the trial was stopped. Out of twelve patients given TKM-130803 who survived the first 48 hours, nine died and three survived. However, most of the patients entering the Ebola Treatment Centre at the time the study was enrolling, which included those given TKM-130803, had very severe Ebola disease, so further studies are needed to assess if the drug might provide a benefit in patients with less severe disease.

Professor Peter Horby, Chief Investigator of the study, said: 'Thanks to the tremendous efforts of everyone involved we now have a much clearer picture of the potential of this drug. We are obviously disappointed that it does not seem to offer a benefit to patients with severe Ebola but it remains to be seen if the drug will help those with less severe illness. The drug was well tolerated by all of the patients and we've learnt a lot about giving the drug to patients with Ebola. Once we get the results of on-going tests of the [drug](#) concentration in the [patients'](#) blood we will have a better understanding of the optimal dose for any further studies.'

**More information:** The paper, Experimental treatment of Ebola Virus Disease with TKM-130803: A single arm phase 2 clinical trial, is published by *PLOS Medicine*, [DOI: 10.1371/journal.pmed.1001997](https://doi.org/10.1371/journal.pmed.1001997)

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