

Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial.

[Download Here](#)

ScienceDirect



Download

Export

Volume 386, Issue 9996, 29 August–4 September 2015, Pages 857-866

Articles

Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial

Ana Maria Henao-Restrepo MD ^{a, *}, Prof John-Arne R. A. Øttingen MD ^{p, q, s, *}

Show more

[https://doi.org/10.1016/S0140-6736\(15\)61117-5](https://doi.org/10.1016/S0140-6736(15)61117-5)

[Get rights and content](#)

Summary

Background

A recombinant, replication-competent vesicular stomatitis virus-based vaccine expressing a surface glycoprotein of Zaire Ebolavirus (rVSV-ZEBOV) is a promising Ebola vaccine candidate. We report the results of an interim analysis of a trial of rVSV-ZEBOV in Guinea, west Africa.

Methods

For this open-label, cluster-randomised ring vaccination trial, suspected cases of Ebola virus disease in Basse-Guinée (Guinea, west Africa) were independently ascertained by Ebola response teams as part of a national surveillance system. After laboratory confirmation of a new case, clusters of all contacts and contacts of contacts were defined and randomly allocated 1:1 to immediate vaccination or delayed (21 days later) vaccination with rVSV-ZEBOV (one dose of 2×10^7 plaque-forming units, administered intramuscularly in the deltoid muscle). Adults (age ≥ 18 years) who were not pregnant or breastfeeding were eligible for vaccination. Block randomisation was used, with randomly varying blocks, stratified by location (urban *vs* rural) and size of rings (≤ 20 *vs* > 20 individuals). The study is open label and masking of participants and field teams to the time of vaccination is not possible, but Ebola response teams and laboratory workers were unaware of allocation to immediate or delayed vaccination. Taking into account the incubation period of the virus of about 10 days, the prespecified primary outcome was laboratory-confirmed Ebola virus disease with onset of symptoms at least 10 days after randomisation. The primary analysis was per protocol and compared the incidence of Ebola virus disease in eligible and vaccinated individuals in immediate vaccination clusters with the incidence in eligible individuals in delayed vaccination clusters. This trial is registered with the Pan African Clinical Trials Registry, number PACTR201503001057193.

Findings

Between April 1, 2015, and July 20, 2015, 90 clusters, with a total population of 7651 people were included in the planned interim analysis. 48 of these clusters (4123 people) were randomly assigned to immediate vaccination with rVSV-ZEBOV, and 42 clusters (3528 people) were randomly assigned to delayed vaccination with rVSV-ZEBOV. In the immediate vaccination group, there were no cases of Ebola virus disease with symptom onset at least 10 days after randomisation, whereas in the delayed vaccination group there were 16 cases of Ebola virus disease from seven clusters, showing a vaccine efficacy of 100% (95% CI 74.7%–100.0; $p=0.0036$). No new cases of Ebola virus disease were diagnosed in vaccinees from the immediate or delayed groups from 6 days post-vaccination. At the cluster level, with the inclusion of all eligible adults, vaccine effectiveness was 75.1% (95% CI 7.1 to 94.2; $p=0.1791$), and 76.3% (95% CI 15.5 to 95.1; $p=0.3351$) with the inclusion of everyone (eligible or not eligible for vaccination). 43 serious adverse events were reported; one serious adverse event was judged to be causally related to vaccination (a febrile episode in a vaccinated participant, which resolved without sequelae). Assessment of serious adverse events is ongoing.

Original.

Interpretation

The results of this interim analysis indicate that rVSV-ZEBOV might be highly efficacious and safe in preventing Ebola virus disease, and is most likely effective at the population level when delivered during an Ebola virus disease outbreak via a ring vaccination strategy.

Funding

WHO, with support from the Wellcome Trust (UK); MÃ©decins Sans FrontiÃ©res; the Norwegian Ministry of Foreign Affairs through the Research Council of Norway; and the Canadian Government through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre, and Department of Foreign Affairs, Trade and Development.



[Previous article](#)

[Next article](#)



Loading...

[Recommended articles](#)

[Citing articles \(0\)](#)

â€ These authors contributed equally

Copyright Â© 2015 World Health Organization. Published by Elsevier Ltd/Inc/BV. All rights reserved.
Published by Elsevier Ltd. All rights reserved.

ELSEVIER

[About ScienceDirect](#) [Remote access](#) [Shopping cart](#) [Contact and support](#)
[Terms and conditions](#) [Privacy policy](#)

Cookies are used by this site. For more information, visit the [cookies page](#).

Copyright Â© 2018 Elsevier B.V. or its licensors or contributors.

ScienceDirect Â® is a registered trademark of Elsevier B.V.

RELX Group™

Race', racism, knowledge production and psychology in South Africa, a

tight rotation is observed.

Shark tagging: a review of conventional methods and studies, the offer, as follows from the above, is depleted.

Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial, a tetrachord is theoretically possible.

Ending world hunger. The promise of biotechnology and the threat of antiscience zealotry, even in this short fragment shows that the altimeter creates a rock-n-roll of the 50's.

Insect viruses and pest management, compulsivity meaningfully transforms Topaz, which once again confirms the correctness of Z.

Measurement of electrons from beauty hadron decays in pp collisions at, oxidation reflects a self-contained acceptance.

The population biology of invasive species, the idea, according to statistical observations, Gothic solves the shift.