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Regulatory Considerations in the Development of Chikungunya Virus Vaccines

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Abstract

Chikungunya virus (CHIKV) is an alphavirus spread by mosquitos. Human Chikungunya disease (CHIK) is distinguished by a sudden onset of high fever, a cutaneous rash, myalgia, and debilitating polyarthralgia. Until recently, the virus was thought to be endemic only to Africa and Asia, but since 2004, CHIK has spread to previously non-endemic regions such as Europe and the Americas, posing a global health threat. Despite the fact that several CHIKV vaccine candidates have been tested in animals and a few have advanced to human clinical trials, no licenced vaccine is currently available for disease prevention. We review recent efforts in CHIKV vaccine development and discuss regulatory considerations for CHIKV vaccine licensure under US FDA regulations in this article.

Keywords: Polyarthralgia • Global • Human • Endemic

Introduction

Chikungunya disease (CHIK) was first identified in 1955, following an outbreak on Tanzania's Malone Plateau in 1952. Chikungunya virus (CHIKV) was first isolated as the CHIK causative agent from a patient during this outbreak in 1953. CHIKV is a parvovirus in the alpha virus genus of the Togaviridae family. The virus has been identified as having three distinct genotypes: West African, East/Central/South African (ECSA), and Asian. CHIKV is spread primarily through the bite of infected Aedes mosquitos. CHIKV is only rarely transmitted from mother to new-born around the time of birth. Human-to-human transmission via blood products or human milk, while theoretically possible, has not been reported to date. Infection typically results in a febrile illness accompanied by myalgia, arthralgia, and cutaneous symptoms [1].

Long-term protective immunity induced by CHIKV infection most likely contributes to long (decades) intervals between epidemics in small rural populations. However, whether these long intervals reflect local circulation of a single genotype or the ability of the immune response to natural infection by one genotype to confer cross-protection against heterologous genotypes is unknown. Human studies have suggested that CHIKV-induced serum neutralising antibodies correlate with viral clearance and long-term protection against subsequent infection and disease. Passively transferred human and mouse anti-CHIKV antibodies appear to be protective in mouse infection models. According to mouse studies, neither CD4+ nor CD8+ T cell subsets appear to play a role in CHIKV replication and dissemination control [2].

Literature Review

The emergence of CHIKV as a significant global health threat emphasises the importance of developing a safe and effective vaccine. Many of the challenges facing the development of vaccines for CHIKV and other emerging pathogens have been discussed in recent reviews by Razz and others. In the sections that follow, we will briefly review current efforts for CHIKV vaccine research and development, focus our discussions on the regulatory considerations associated with CHIKV vaccine development, and outline regulatory requirements for demonstrating the efficacy and safety of CHIKV vaccine candidates to support licensure in the United States [3,4].

Discussion

There is currently no licenced vaccine available to prevent CHIK. Inactivated viruses live attenuated viruses, chimeric viruses, replication defective vectored vaccines, recombinant DNA vaccines, subunit vaccines, and virus-like particle (VLP) vaccines are among the vaccine candidates under development. While the majority of these investigational vaccines have shown immunogenicity and/or protection against lethal challenge in animals, only a few have advanced to human clinical trials [5].

In a phase 1 clinical trial with 42 healthy participants, the safety and immunogenicity of a measles virus-based CHIKV vaccine (MV-CHIK) were assessed. The MV-CHIK vaccine was created by inserting the structural genes (C, E3, E2, 6K, and E1) of an ECSA genotype virus into a vector derived from the Schwarz strain of measles virus, which is included in the Priory measles-mumps-rubella vaccine [6,7].

Conclusion

There is currently no licenced vaccine available to prevent CHIK. Inactivated viruses live attenuated viruses, chimeric viruses, replication defective vectored vaccines, recombinant DNA vaccines, subunit vaccines, and virus-like particle (VLP) vaccines are among the vaccine candidates under development. While the majority of these investigational vaccines have shown immunogenicity and/or protection against lethal challenge in animals, only a few have advanced to human clinical trials..

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Conflict of Interest

There is no conflict of interest by author.

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