

An Attenuated EHEC and Clostridial Toxins TcdA and TcdB Based Vaccine for Clostridium Difficile Associated Disease (CDAD)

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Technology description

In the absence of any existing vaccine to combat *C. difficile*, a live oral vaccine designed to induce protective mucosal, and systemic, immunity to *C. difficile* toxins in order to prevent CDAD has been developed.

Background

Clostridium difficile associated disease (CDAD) is the leading cause of infectious diarrhea in hospitalized patients, with the incidence doubling since 1996. With rising incidence, is an associated rise in mortality caused from contraction of this infection, as the virulence of the *C. difficile* strains grows accompanied by an increase in host vulnerability. The occurrence of CDAD in hospitalized patients leads to high incremental costs for hospitalization in individuals who develop the disease, with hospitalization costs ranging from \$3-5,000 for primary infection and \$13-18,000 for recurrent infection, in the United States. It is expected that both the incidence and complexity of this infection is likely to increase, including a rise in antibiotic resistance, thus there is a need for novel therapeutic and prophylactic approaches to combat this epidemic.

Technology Description

In the absence of any existing vaccine to combat *C. difficile*, researchers at the University of New Mexico, have developed a live oral vaccine designed to induce protective mucosal, and systemic, immunity to *C. difficile* toxins in order to prevent CDAD. Utilizing previously developed and patent pending technology, researchers have based this vaccine on a genetically attenuated strain of *E. coli* which serves as a vector to deliver antigens of other important pathogens such as *C. difficile*. This vaccine strain contains no toxin activity, but retains antigenic components of important *E. coli* virulence determinants. Into this strain, researchers have introduced the clostridial toxins A and B (TcdA and TcdB), which through the structure of incorporation are displayed on the surface of the vector organism, which tests have shown to be the best location for inducing mucosal immunity. Further developments of this vaccine will potentially allow for intranasal delivery, making its immunity inducing abilities more effective. Nevertheless, this

vaccine offers great hope for combating the rising incidence of CDAD where for both in initial and in recurrent episodes after treatment, this infection could be reversed.

Advantages

Utilizing previously developed and patent pending technology, researchers have based this vaccine on a genetically attenuated strain of E. coli which serves as a vector to deliver antigens of other important pathogens such as C. difficile. This vaccine strain contains no toxin activity, but retains antigenic components of important E.coli virulence determinants.

Utilizes already existing and proven technology of attenuated E. coli vaccine constructs

Vaccine is structured so as to have clostridial toxins located for highest rate of inducing mucosal immunity

Vaccine E. coli strain contains no toxin activity

Increasing incidence of CDAD, both in initial and in recurrent episodes after treatment, holds promise to be reversed

Institution

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