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A phase II, randomized, safety and immunogenicity study of a re-derived, live-attenuated dengue virus vaccine in healthy adults

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Abstract

Two formulations of a new live tetravalent dengue virus (DENV) vaccine produced using re-derived master seeds from a precursor vaccine and that same precursor vaccine as a control were compared in a placebo-controlled, randomized, observer-blind, phase II trial of 86 healthy adults. Two vaccine doses were administered 6 months apart; a third dose was offered to a subset. Symptoms and signs of dengue-like illness reported after vaccination were mild to moderate, transient, and occurred with similar frequency among recipients of the new DENV vaccine and placebo, except for rash. Neither dengue nor vaccine-related serious adverse events were reported. The first DENV vaccine dose was moderately immunogenic; the second dose increased the potency and breadth of the neutralizing antibody response. Tetravalent response rates to the new formulations were 60% and 66.7% in unprimed subjects. A third dose did not increase tetravalent antibody rates. The new DENV vaccine candidates merit additional evaluation.

Trial registration: [ClinicalTrials.gov](#) [NCT00350337](#).

Figures



Figure 1. Subject disposition. ATP = according...

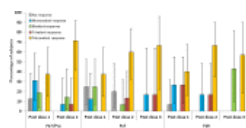


Figure 2. Mono-, bi-, tri-, and tetra-valent...

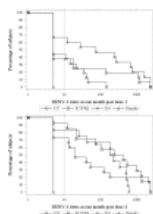


Figure 3. Reverse cumulative curves of DENV-1...

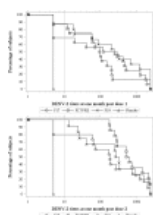


Figure 4. Reverse cumulative curves of DENV-2...

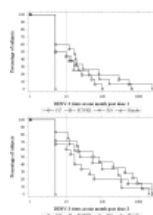


Figure 5. Reverse cumulative curves of DENV-3...

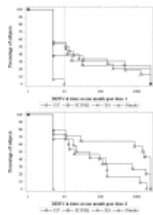


Figure 6. Reverse cumulative curves of DENV-4...

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AB - Two formulations of a new live tetravalent dengue virus (DENV) vaccine using re-derived master seeds from a precursor vaccine and that same precursor vaccine as a control were compared in a placebo-controlled, randomized, observer-blind, phase II trial of 86 healthy adults. Two vaccine doses were administered 6 months apart; a third dose was offered to a subset. Symptomatic signs of dengue-like illness reported after vaccination were mild to moderate, transient, and occurred with similar frequency among recipients of the vaccine and placebo, except for rash. Neither dengue nor vaccine-related adverse events were reported. The first DENV vaccine dose was moderately immunogenic; the second dose increased the potency and breadth of the neutralizing antibody response. Tetravalent response rates to the new formulations were 60% and 66.7% in unprimed subjects. A third dose did not increase tetravalent antibody rates. The new DENV vaccine candidates merit additional evaluation.
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PT - Randomized Controlled Trial
DEP - 20121203
TA - Am J Trop Med Hyg
JT - The American journal of tropical medicine and hygiene
JID - 0370507
RN - 0 (Dengue Vaccines)
RN - 0 (Placebos)
SB - IM
MH - Adult
MH - Dengue Vaccines/adverse effects/immunology/*therapeutic use
MH - Dengue Virus/*immunology
MH - Humans
MH - Placebos
PMC - PMC3541749
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