

Abstract

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A Novel, Vero Cell Derived, Purified, Inactivated Japanese Encephalitis Virus Vaccine: Results of a Randomized Controlled Phase 3 Trial.

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Background: Vaccination against Japanese Encephalitis Virus (JEV) is the most important measure to prevent infection among residents and visitors in endemic areas. A second generation vaccine, based on the purified, inactivated JEV strain SA₁₄₋₁₄₋₂ adjuvanted with aluminum hydroxide, is in late stage development by Intercell AG. This is the first report on the immunogenicity and safety findings of its pivotal Phase 3 trial.

Aims: This study aims to compare safety and immunogenicity of the Intercell JEV vaccine (IC51) with that of the currently licensed, mouse brain derived vaccine.

Subjects and Methods: The study was performed in a multicenter, multinational, observer blinded, randomized controlled trial. 868 subjects were randomized in 10 study sites in the U.S., in Germany and in Austria, and received either the Intercell JEV vaccine (2 doses of 6 mcg, 4 weeks apart, I.M.) or JE-VAX® in its recommended 3 dose schedule (days 0, 7, 28; S.C.). The co-primary endpoint was non-inferiority of the Intercell vaccine in terms of neutralizing antibody titers (GMTs) and seroconversion rates (SCR) at day 56, as assessed by a Plaque Reduction Neutralization Test (PRNT).

Results: Safety: Local tolerability and general safety of this investigational new vaccine proved to be good and comparable to licensed adjuvanted inactivated vaccines. There was one serious adverse effect reported in the trial. It was assessed by the investigator as being unlikely related to the study medication. **Immunogenicity:** SCR of the Intercell Vaccine was 96 % compared to 94% of JE-VAX®. The risk difference estimator (Mantel-Haenzel) was 0.8 % (95% CI: -1.6 to 3.2 %). GMT of the Intercell Vaccine was 244 (SD = 1,163), compared to 102 (SD = 221) of JE-VAX®. The estimated GMT ratio (ANOVA) was 2.3 (95% CI: 2.0 to 2.7). Based on these results, the Intercell JEV vaccine was non-inferior compared with JE-VAX® in terms of SCR and GMT at the 0.05 significance level.

Conclusion: This pivotal Phase 3 trial demonstrated an excellent safety and immunogenicity profile for the Intercell JEV vaccine.