

The vaccine candidate *Vibrio cholerae* 638, was safe and immunogenic in healthy children and adolescents, from Cienfuegos province, Cuba

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A clinical trial was conducted to assess the safety, reactogenicity and immunogenicity of the live attenuated vaccine candidate *Vibrio cholerae* 638 (CV638), in healthy children and adolescents from both sexes, ranging 5 to 17 years old from the Cienfuegos Province, Cuba. An oral single dose of CV638 was administered to 40 out of 54 subjects of the study group, and the 14 subject of the control group, received the placebo. No serious adverse events nor clinical laboratory results out of range with clinical significance were reported. The percentage of volunteers with any adverse event did not reach significant differences among groups, being mild in most of the subjects. The most frequent adverse events in the group that ingested CV638 were meteorism (25.64%) and vomit (17.95%), while in the group that ingested placebo were fever (21.46%) and abdominal pain (4.29%). The one hundred percent of 10 to 17 years old adolescents, the other ones of 9 to 11 years old and the ones 5 to 8 years old children of the study group, seroconverted at 14 days after to be ingested the CV638. It is concluded that CV638 is safe, little reactogenic, and immunogenic in healthy children and adolescents of both sexes.

Biography:

Hilda García has completed his Master's Degree in Bacteriological and Micological Sciences and Doctor's Degree in Health Science Pedro Kouri Institute (IPK), Cuba. 1996-1997 & 2000-2004

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His Research is based on Genetic manipulation of *Vibrio cholerae* for vaccine development. Construction of Live attenuated El Tor Candidate Vaccine Strains. Selection of attenuated *Vibrio cholerae* strains to obtain oral attenuated candidate vaccines against cholera. Process development for Cuban cholera vaccine based on the attenuated strain *Vibrio cholerae* 638. Clinical evaluation of a vaccine candidate based on the attenuated strain 638 *Vibrio cholerae* O1 El Tor Ogawa. Total publications 40