

VAC_04 - A phase II. III clinical trial to assess immunogenicity, reactogenicity and safety of the measles, rubella vaccine, produced by Bio-Manguinhos

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Introduction: Measles and rubella are diseases caused by viruses that can cause hospitalizations, deaths, and congenital malformations. Although they have already been eliminated from some countries, others have yet to introduce the primary two-dose vaccination schedule. The study aimed to evaluate the immunogenicity and reactogenicity of the measles and rubella vaccine produced by Bio-Manguinhos / Fiocruz. With the approval of regulatory agency and WHO, it will be possible to nationally distribute the Bio-Manguinhos double viral vaccine, with its possible use by the National Immunization Program, as well as its export to meet WHO recommendations for the elimination of measles and rubella.

Objective: To evaluate the immunogenicity, in terms of the proportion of seroconversion, of a dose of the BIOMR vaccine, in infants of about 11 months of age, in relation to the MMR vaccine, for the measles and rubella components. To evaluate the reactogenicity of a dose of the vaccine. BIOMR, in 11-month-old infants. To evaluate the immunogenicity, in terms of the geometric mean of antibody titers, of a dose of the BIOMR vaccine, in infants about 11 months of age, in relation to the MMR vaccine, for the measles and rubella components. To evaluate the safety of a dose of the BIOMR vaccine, in infants aged 11 months, in relation to the occurrence of unsolicited adverse events in the 30 days after vaccination and serious adverse events throughout the participation in the study.

Methodology: A clinical trial, controlled, randomized and double-blind, whose main hypothesis was that the BIOMR vaccine is not inferior in terms of immunogenicity to the comparator, the MMR vaccine from Bio-Manguinhos, with a reactogenicity profile similar to that expected for its comparator. Reactogenicity was assessed after recording adverse events in the Adverse Events Diary, and immunogenicity was assessed by collecting samples and carrying out the immunoenzymatic assay.

Results: A total of 432 infants of both sexes, 11 months old, living in the area covered by the research centers, in Natal and Rio de Janeiro, who met the eligibility criteria were included. The study lasted from November 2018 to December 2019. Thirty infants presented neutropenia after vaccination, but with return to pre-immunization levels, there was no serious adverse event with causality confirming vaccination, and the seroconversion of the components of the viral double vaccine did not was statistically different from the MMR vaccine.

Conclusion: The double viral vaccine from Bio-Manguinhos is safe, with a profile of reactogenicity and immunogenicity similar to that of the MMR vaccine. The results of the study were sent to ANVISA, and then will be sent to WHO.

Keywords: measles; rubella; vaccine