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Comparison of three sample size estimation methods for non-inferiority vaccine trials with multiple continuous co-primary endpoints

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Combination vaccines have been extensively used for decades and bring together the issue of intersection-union. To make up for the reduction in statistical power at the study level, researchers have to increase the study sample size. In view of the nature of immunogenicity variables, we use the geometric mean concentration of immune response after vaccination as immunologic endpoint and compare three sample size calculation methods: the "Inflation factors" method, the "Incrementing method" and the Bonferroni correction method when there are multiple continuous co-primary endpoints. The parameters are set according to the actual situation of combination vaccines and the simulation results were used as reference. The present study demonstrates that the "Incrementing method", the Bonferroni corrected method and the "Inflation factors method" are all available when the effect size of each endpoint is comparable and there is no or weak correlation between each endpoint. When there is a valid difference of effect sizes among endpoints, the "Incrementing method" performs better.

Biography

Yang Jiaying has her expertise in research design and statistical analysis of vaccines and drug clinical trials. She has conducted in-depth research in the past few years in the randomization of subjects and the calculation of the sample size of tirals when there were multiple co-primary endpoints, and has been funded by the Fundamental Research Funds for the Central Universities and the Postgraduate Research Practice Innovation Program of Jiangsu Province.

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