
Popular repeated significance type of sequential tests for binary responses

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Fixed sample clinical trials involve humans that are accumulated over a considerably large period of time in order to achieve the pre-specified sample size calculated prior to the study. These designs are somewhat impractical as they do not address economical and some ethical issues such as the decisions are made using a greater number of patients. Thus, for the reason being one of economical and ethical, sequential designs come into practice. At interim inspection, sequential designs either stop or continue. These usually have lesser number of patients, leading to saving in cost and time while improving ethical issues. When the response is binary with the interest of clarifying the significant difference between two treatments, the application of the binomial test in sequential framework is merited. This research aims to compare three repeated significant type of sequential tests namely, Pocock, O'Brien-Fleming and Lan & DeMets tests to specify the best sequential design involving binary data. These were compared using type I error, power, mean information and average duration to stopping the trial by using simulation studies developed in software SAS Version 9.4. To ensure the practicability of each design, the three designs were applied to a real-world dataset which comprises information on U.S. diabetics. An envisaged feature of early termination of the trial at early stages successfully appeared allowing the sample size to be reduced. All designs provided type I error rates which are maintained within the acceptable region while keeping high power. An appropriate value was assigned to each design property while introducing a Likert scale and the design that reached the highest total score was selected as the best. Eventually, the Lan and DeMets design is marginally superior to the other designs studied while ensuring all designs are feasible in practice.

Keywords - Sequential designs, Repeated significant type tests, Binary, Type I error, Power

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