Estimation of Number of Subjects Required for Comparison of Drug versus Control in Adaptive Designs

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Abstract

***Introduction**: Adaptive designs have often been proposed as a way of using accruing data to affect future allocation scheme in clinical trials. The goal is to assign more patients to the better treatment. To implement clinical trials efficiently, sample size must be estimated in advance. In adaptive design, it is difficult to calculate the required sample size, because the allocation probabilities keep changing during the course of the trials. **Methods**: We focus on the sample size of two-arm (drug versus control) clinical trials. Based on its asymptotic properties, a formula of calculating sample size is derived for the randomised play-the-winner rule. We also compare sample size and power between the randomised play-the-winner rule and equal allocation. Some simulation studies illustrate the operating characteristics of the designs. **Results and Discussion**: The required sample size of the randomised play-the-winner rule is slightly larger than that of the equal allocation design in most cases. The randomised play-the-winner rule is recommended for ethical reasons.*

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***Key words**: Power, Randomised play-the-winner rule, Sample size, Sequential design*

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