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Adaptive clinical trials: A review article

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Objective: To provide a brief overview of adaptive clinical trials.

Materials and Methods: The information is collected from guidance for industry: Adaptive design clinical trials for drugs and biologics, a draft guidance by food and drug administration and some review articles.

Background: The clinical trials community has a never ending search for dependable and reliable ways to improve clinical research. This exploration has led to considerable interest in adaptive clinical trial designs which provide the flexibility to adjust trial characteristics on the basis of data reviewed at interim stages. However it is a concern that the actual patient population after adaptation could deviate from the originally target patient population and consequently overall type I error (to erroneously claim efficacy for an ineffective drug) rate may not be controlled. In this article, several commonly considered adaptive designs in clinical trials are reviewed.

Conclusion: There is growing interest in the use of adaptive clinical trial designs. However, a number of logistical barriers need to be addressed. In order to obtain the potential advantages of adaptive clinical trials, researchers should have complete knowledge about the types, barriers and advantages of the adaptive clinical trial designs.

Biography

Balaji V has completed his MBBS at the age of 23 years from Tamil Nadu Dr. M. G. R. Medical University and is currently pursuing Post-graduation in Pharmacology from Rajiv Gandhi University of Health & Sciences. Currently, he is working on two research projects namely anticonvulsant property of Nebivolol and drug utilization pattern in MICU among geriatric population.

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