

(41) Byrom W Brown (1978)

Statistical Controversies in the Design of Clinical Trials

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Preamble

The book arose from revision of an invited lecture for clinicians and statisticians participating in cooperative clinical trials in the Veterans Hospitals, Chicago, 18 August 1977. It is available online at (<http://statistics.stanford.edu/sites/g/files/sbiybj6031/f/BIO%2037.pdf>).

An earlier Technical Report (no. 21) in the same series, Biostatistics Case Book, volume 1 (1976) presented some interesting design and analysis problems of biostatistical applications; it was followed by Volume 2 (Technical Report no. 36) in 1978. Both are available online.

Aims

My purpose in these remarks is to deal with some of the main statistical controversies that arise in the design of clinical studies. The questions I have chosen to discuss are questions that arise in the design phase of cooperative clinical trials as the clinicians and statisticians begin to formulate the details of the hypothesis and the procedures to be used in putting the hypothesis to test. I am concentrating on the five areas that seem to me most closely related to early design considerations (pages 1 and 3).

Contents (ii+28 pages)

Preamble (untitled)

1. Timing of the randomised cooperative clinical trial
2. Choice of patients and treatment regimens
3. Randomization and stratification
4. Crossover designs
5. Calculation of required sample size

References

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