(65) Christopher J Bulpitt (1983) Randomised Controlled Clinical Trials

The Hague: Martinus Nijhoff

Preamble

A second edition of this book was published in 1996.

Aims

Bradford Hill has defined a clinical trial as "A carefully and ethically designed experiment with the aim of answering some precisely framed question". This definition specifies a careful design and requires the provision of adequate controls. Random allocation of treatments to subjects is important to ensure that the treated and control groups are similar. Therefore, this book is entitled Randomised Controlled Clinical Trials. We can define a randomised controlled trial by rewriting Bradford Hill's definition as follows, "A carefully and ethically designed experiment which includes the provision of adequate and appropriate controls by a process of randomisation, so that precisely framed questions can be answered." I am a firm advocate of randomised controlled clinical trials but intend to give a balanced view of the advantages and disadvantages of these ethical experiments. This book is directed primarily at the medical research worker, although certain chapters may find a wider application. When discussing a randomised controlled trial, it is neither practicable nor desirable to divorce theory from practice, however the first ten chapters concentrate mainly on theory, and the remainder focus on practice. This book is meant to serve both as a reference manual and a practical guide to the design and performance of a trial. (Preface, page vii).

Contents (xi+262 pages)

- 1) Introduction
- 2) The history of controlled trials
- 3) Ethical considerations
- 4) The objectives of a randomised controlled trial
- 5) Validity of the results
- 6) Recruitment of subjects
- 7) How to ensure that the control and treated patients are similar in all important respects
- 8) How to ensure that the results are free of bias
- 9) The variability of results
- 10) How many subjects are required for a trial
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