

(40) P Armitage, D Bardelli, DAG Galton, EA Gehan, GA Higgins, K Magnus, AB Miller, SJ Pocock, and R Saracci (eds) (1978)

Methods and Impact of Controlled Therapeutic Trials in Cancer: part I

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Preamble

The publication of the survey of all trials registered at the Information Office of UICC during the period 1972 to early 1975 appeared in two parts. The first part as here and the second part as *Controlled Therapeutic Trials in Cancer (R Flamant, C Fohanno (eds))*, UICC Technical Report Series, 1978).

Aims

At its meeting in May 1975 the UICC Project on Controlled Therapeutic Trials decided to devote its activities to the improvement of methodology "so that trials are easier to conduct and lead to more valid conclusions". For this purpose a number of subjects were selected, which were related to the major difficulties encountered both by physicians and statisticians involved in cancer clinical trials. The subjects were distributed among the members of the Project who were advised to invite people from outside to co-operate, should they feel the need for it. A meeting gathering all those who had participated in the various surveys was convened in April 1978 to discuss the results and prepare their publication. Two aspects of the working method deserve special attention. First, a very practical approach has been adopted, which consisted in founding the surveys on trials actually conducted, whether in progress or published. Second, all surveys have given rise to discussions between physicians and statisticians, whose points of view do not always coincide (Introduction, page 1).

Contents (viii+135 pages)

[Sub-headings omitted]

UICC Programme on clinical oncology: Project on controlled therapeutic trials (1974 – 1978)

Introduction (R Flamant)

The size of cancer clinical trials: an international survey (SJ Pocock, P Armitage, DAG Galton)

Introduction

Survey methods

The response

Types of trial

Pre-specification of sample size

Pre-specification of periods of accrual and follow-up

Size of treatment difference considered in design

Progress of trial so far

Interim analysis of results

Method of randomisation

Publication of results

Additional comments from investigators

Multi-centre trials

Discussion

References

Acknowledgments

Appendix: Survey of the size of clinical trials

Adjustment for prognostic factors in the analysis of clinical studies (EA Gehan)

- I. Introduction
- II. Methods
- III. Examples from studies of breast cancer
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Measuring the quality of life in cancer clinical trials: a sample survey of published trials
(D Bardelli, R Saracci)

- Introduction
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- Results
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- References

Methodology of controlled prophylactic trials in cancer (Knut Magnus,
Anthony B Miller)

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- Study population
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- Randomization
- Stratification
- Sample size considerations
- Compliance
- Adverse effects
- Criteria for evaluation of efficacy
- Follow-up
- Analysis and interpretation
- Conclusion
- References

Legal and ethical problems in the conduct of therapeutic trials: 1978 (GA Higgins)

Authors

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