

20 Clinical trials

The clinical trial is an instrument designed to assess the effectiveness of potentially new or altered interventions that involve a wide range of clinical activity.

Trials frequently involve drug therapy, but may address new devices, surgical procedures, treatment by external instrumentation (e.g. radiotherapy), or psychosocial aspects of clinical management.¹

Commonly, the study question is whether a new treatment is better than the old one. It is customary to compare each new treatment group with a control group, the members of which must be offered treatment matching the best standard currently available for their consideration before joining the trial.¹

The randomised clinical trial (RCT), which involves random allocation of patients to their treatment or control group, is becoming the 'gold standard' for assessment of new management processes.

Clinical trials involve significant funding and require the informed consent from patients and frequently, the involvement of a number of centres and health professionals to obtain an appropriate number of subjects to ensure sound statistical power.

The conduct of trials by cooperative groups of trialists is the most likely way to advance evidence-based medicine through well-designed protocols and rigorous evaluation.²

However, in our community some people are concerned about RCTs, believing that patients involved in such trials may be at risk from factors that would not occur in treatment outside a trial. On the other hand, others see participation in an RCT as being of benefit to the trial subject and probably an optimal way of receiving the best contemporary care and clinical oversight.

A recent Cochrane Review assessed the effect of participation in RCTs ('trial effects') independent both of the effects of the clinical treatments being compared ('treatment effects') and any differences between patients who participated in RCTs and those who did not.³

The outcome of this review led its authors to conclude that there is no greater risk from participating in RCTs than there is from being treated outside an RCT. The authors considered that the belief or assertion that results of RCTs cannot be applied to usual practice is challenged by the review.² This outcome would appear to provide a sound basis for clinicians to offer participation in RCTs to their patients.

Any uncertainty about the effects of treatment can best be resolved through a randomised trial as long as the eligibility criteria for the trial match the patient population seen in usual practice, or the trial treatment is applied only to patients who match the eligibility criteria.⁴

Evidence summary	Level	Reference
Outcomes for patients who participate in RCTs on average do not differ from those of patients who receive similar treatments and do not participate in a trial	I	2

Recommendation		Grade
1. Patients can be informed that they are unlikely to be disadvantaged by participation in an RCT		A

20.1 Good practice point

- Given the lack of evidence in treating melanoma, patients be given the opportunity to enter clinical trials

References

1. The Cancer Council Victoria. About Clinical Trials. Available from <http://www.cancervic.org.au/browse.asp?ContainerID=about_clinical_trials> accessed 1 September 2007.
2. Vist GE, Hagen KB, Devereaux PJ, Bryant D, Kristoffersen DT, Oxman AD. Outcomes of patients who participate in randomised controlled trials compared to similar patients receiving similar interventions who do not participate. *Cochrane Database Syst Rev* 2007;(2):MR000009.
3. Optimising Cancer Care in Australia. 1–122. 2002. Melbourne. Available from <http://www.cosa.org.au/documents/optim_Cancer_Care_final.pdf>. Clinical Oncology Society of Australia, The Cancer Council Australia and The National Cancer Control Initiative.
4. Kunz R, Vist G, Oxman AD. Randomisation to protect against selection bias in healthcare trials. *Cochrane Database Syst Rev* 2007;(2):MR000012.