

Symposium Poster**Controlled post-marketing surveillance studies
– an innovative design for evaluating clinical effectiveness****E. Ernst**

One important issue for establishing phytotherapy is the demonstration of clinical effectiveness. Post-marketing surveillance studies have traditionally been employed for this purpose, but they have rightly been criticised for being wide open to bias. Randomised controlled trials are clearly the gold standard, yet they are at best difficult and at worst not possible to conduct. An innovative compromise between the desirable and the feasible could be a “controlled post-marketing surveillance study” [1]. Typically such an investigation would involve many centres. Large groups of patients with a given condition are enrolled and prescribed either the experimental remedy (group A) or remedies freely chosen by the treating physicians (group B). To ensure comparability of group A and B, patients could be matched according to relevant criteria. Both parallel groups would subsequently be treated during a pre-defined time period and evaluated according to pre-defined time period and evaluated according to pre-defined endpoints – much like any other

clinical trial design. The advantages of this novel design are numerous: it presents fewer logistic problems than a randomised controlled trial; it incurs less cost per patient; it allows recruitment of large sample sizes; the ethical problems of placebo treatments are avoided; it is legally permissible in most countries; it provides comparative data on effectiveness and safety from comparable groups of patients; its statistical evaluation is straight forward. We conclude that the “controlled post-marketing surveillance study” may offer a reasonable solution to (some of) the problems in assessing phytotherapeutics.

1. Ernst E, März R, Sieder Ch. A controlled multicentre study of herbal versus synthetic secretolytic drugs for acute bronchitis. *Phytomedicine* 1997;4:287-293.

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