Records

Key Passage(s) JLL Article(s) Context

Download key passages/title pages as a PDF

Djulbegovic B, Lacevic M, Cantor A, Fields KK, Bennett CL, Adams JR, Kuderer NM, Lyman GH (2000). The uncertainty principle and industry-sponsored research. Lancet 356:635-638.

Key passages

The uncertainty principle and industry-sponsored research

Benjamin Djulbegovic, Mensura Lacevic, Alan Cantor, Karen K Fields, Charles L Bennett, Jared R Adams, Nicole M Kuderer, Gary H Lyman

Summary

Background Reporting of pharmaceutical-industry-sponsored randomised clinical trials often result in biased findings, either due to selective reporting of studies with non-equivalent arms or publication of low-quality papers, wherein unfavourable results are incompletely described. A randomised trial should be conducted only if there is substantial uncertainty about the relative value of one treatment versus another. Studies in which intervention and control are thought to be non-equivalent violates the uncertainty principle.

Methods We examined the quality of 136 published randomised trials that focused on one disease category (multiple myeloma) and adherence to the uncertainty principle. To evaluate whether the uncertainty principle was upheld, we compared the number of studies favouring experimental treatments over standard ones. We analysed data according to the source of funding.

Findings Trials funded solely or in part by 35 profit-making organisations had a trend toward higher quality scores (mean 2·94 [SD 1·3]; median 3) than randomised trials supported by 95 governmental or other non-profit organisations (2·4 [0·8]; 2; p=0·06). Overall, the uncertainty principle was upheld, with 44% of randomised trials favouring standard treatments and 56% innovative treatments (p=0·17); mean and median preference evaluation scores were 3·7 (1·0) and 4. However, when the analysis was done according to the source of funding, studies funded by non-profit organisations maintained equipoise favouring new therapies over standard ones (47% *vs* 53%; p=0·608) to a greater extent than randomised trials supported solely or in part by profit-making organisations (74% *vs* 26%; p=0·004).

Interpretation The reported bias in research sponsored by the pharmaceutical industry may be a consequence of violations of the uncertainty principle. Sponsors of clinical trials should be encouraged to report all results and to choose appropriate comparative controls.

Lancet 2000; **356:** 635–38