

Letter

Equipoise, design bias and randomized controlled trials: the elusive ethics of new drugs – a comment

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We read with interest the article by Fries and Krishnan about equipoise, design bias and randomized controlled trials [1]. It is important to stress that equipoise is not the principle underlying company-driven clinical trials, which are doubtlessly necessary and useful for medical progress. As a rule, companies' clinical research departments cannot afford the risk that their hypotheses are invalid and, thus, that their trials will fail. Furthermore, equipoise in non-commercial trials is a very complex issue, which we do not intend to discuss here. So, "positive expected outcomes" seems to be an interesting and realistic alternative to equipoise.

We cannot, however, agree with the authors' control group considerations. From our point of view, it is not acceptable for subjects assigned to a control group to be denied standard treatment, even if the mean expected outcome (expected outcome in the verum group plus expected outcome in the control group divided by two) is positive. One of the authors' arguments for the admissibility of control group treatments below clinical standard is that patients are autonomous and can make decisions on their own. In the case of most health problems, patients are under enormous mental pressure and are not necessarily able to weigh-up the pros and cons in an objective way. Furthermore, the feasibility of a placebo-controlled trial should not depend on a company's estimation of by how far the new treatment will exceed standard treatment. Finally, and this is the essential point, it is dangerous to undermine the patients' right to get the best possible treatment. In most European countries, social security systems enable patients to get the best possible treatment. It is hard to understand why this level of treatment should be neglected in clinical trials.

In conclusion, we think that the principle of "positive expected outcomes" is an interesting and realistic approach but we should not ignore the ethical principle of "best possible treatment for every patient".

Competing interests

The author(s) declare that they have no competing interests.

Reference

1. Fries JF, Krishnan E: **Equipoise, design bias and randomized controlled trials: the elusive ethics of new drugs.** *Arthritis Res Ther* 2004, **6**:R250-R255.