

The improper use of research placebos

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Rationale Reasons given for the routine use of placebos in Phase III clinical research are not convincing. Ethically inadequate strategies such as using placebos and recruiting the mentally incompetent for non-therapeutic research are allegedly permissible because research is purportedly aimed at benefiting the common weal. Method and results A review of current literature concludes that placebos are not equivalent to inactive substances, as has been amply shown in clinical use; in research settings they may actually be harmful, for patients recruited as research subjects often develop expectations that are all the more frustrated if they receive a control substance that is not therapeutic but may show unexpected side effects. Supposedly inert control substances have met with strong opposition, for patients are placed at risk of becoming therapeutic orphans when their current medication is withdrawn and they have a 50% chance of being randomized to the inactive control arm. Using place