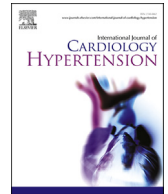




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Hypertension Highlights

Clinical trials may be unethical in certain instances

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ABSTRACT

After review of the literature, I conclude that clinical trials may be unethical.

Ethics or moral philosophy is a branch of philosophy that “involves systematizing, defending, and recommending concepts of right and wrong behavior” [1].

Ethics seeks to resolve questions of human morality by defining concepts such as good and evil, right and wrong, virtue and vice, justice and crime. As a field of intellectual inquiry, moral philosophy also is related to the fields of moral psychology, descriptive ethics, and value theory [1,2].

The author of this commentary has participated in randomized clinical trials as principal investigator, as a member of ethics committees and as a trial participant. A theoretical model where the possibility of unethical behavior is maximized is described below. Clinical trials may be unethical because participants in the clinical trials assume equipoise i.e. that the chance of finding a benefit or a harm are equal and written signed consents are required. In this theoretical model clinical trials were considered unethical by maximizing the possibility of theoretically high adverse outcomes. These theoretical clinical trials may be considered unethical since they hide their lack of ethics by using fancy mathematics and famous names (Lans DeMets) [3]. Clinical trials may be unethical because they use the p value of less than 0.05 with the same probability for harms and benefits [4–9]. Ethical monitoring committees, Institutional Review Boards, and Data Safety Monitoring Boards are critical aspects of clinical trials to ensure that the participants and the public are well served.

Declaration of competing interest

The author declares that he has no competing relevant interests.

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