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The ethics of the placebo in clinical trials

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Clinical trials are scientific evaluations of medical interventions for the treatment of somatic or psychological conditions that provide an analysis of the quality, safety and efficacy of particular products or a method of evaluating two products for their comparative value. Clinical trials can be randomized and non-randomized. A randomized clinical trial comprises two (or possibly more) experimental or treatment groups in which trial subjects are randomly assigned into different groups to ensure internal validity. If there are two groups, one group receives the product being studied and the other group receives the standard therapy/product or a placebo. There are four cases in which a placebo control design, when scientifically appropriate, is also considered ethically acceptable. First, placebo control trials are acceptable when there is no proven effective intervention for the condition under study or when placebo is compared against an investigational treatment added on to established treatment. Second, placebo is acceptable when withholding an established, effective intervention would expose subjects to at most, temporary discomfort or delay in relief of symptoms, as noted in the Council of International Organizations of Medical Sciences'. A third justification is sometimes invoked to justify placebo controls in trials of new treatments for conditions whose response to both established treatments and placebo is highly variable. Finally, compelling methodological reasons for use of placebo and participants are not deprived of interventions they would otherwise receive and research intended to develop interventions that will benefit the host population. Invoking the principle of clinical equipoise, opponents of placebo-controlled trials in the face of proven effective treatment argue that they (1) violate the therapeutic obligation of physicians to offer optimal medical care and (2) lack both scientific and clinical merit. As a conclusion placebo controls are ethically justifiable when they are supported by sound methodological considerations and their use does not expose research participants to excessive risks of harm.

Biography

Grigorios Leon is the President of Hellenic Society of Forensic Medicine and is a Representative (Deputy) of Greece in the European Council of Legal Medicine. He is on the lists of experts in the County Courts of Law (Athens, Piraeus, etc.). He is a Graduate (MD) of the Medical School of the University of Rome "La Sapienza", where he obtained two Master degrees (MSc). In 2009, he received his PhD from the Medical School of the National and Kapodistrian University of Athens. His research interests are in the areas of forensic pathology, medical deontology and bioethics.

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