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UNIVERSITATEA DE VEST "VASILE GOLDIȘ" din ARAD

Placebo in Controlled Clinical Trials: Where Do We Stand?

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The use of placebo in clinical studies is a matter of everlasting debate. It can be argued that placebo-controlled trials could be seen as the most exact method of evaluating the safety and efficacy of new treatment options. Oppositely, quite a few authors have consistently argued that placebo-controlled studies are unethical if already approved and effective therapy is available for the condition being of research interest. The questions of equipoise, research problem justification, methodological necessities including new artificial intelligence technologies, adequately presented and appreciated information through informed consent, the inclusion of vulnerable populations, inconsistent regulatory recommendations, and finally the question of exposing participants to unacceptable risks, these all remain significant issues in placebo-controlled designs. Therefore, this book aims to summarize the existing knowledge, as well as arguments for, and against the use of placebo in clinical studies, and to provide some pragmatic suggestions for developing and conducting placebo-controlled studies that can be ethically acceptable.

Quite a few articles and books have been published in this field, yet new developments in artificial intelligence-related investigations, updated worldwide and corresponding national guidelines for placebo-controlled investigations, and rapid development of biological drugs including biosimilars, all require special attention from the pharmaceutical industry and medical practitioners involved in placebo-controlled clinical trials.

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Proposed topics

1. Placebo – general considerations: placebo throughout history; placebo and physiological processes; placebo and psychological/social harm.
2. Clinical studies and placebo: 'phase Ib/II studies; placebo and phase III studies; placebo and vulnerable participants; placebo and methodological quality; placebo and artificial intelligence.
3. Ethics and placebo: placebo and informed consent; placebo and clinical study rationale; placebo and the Declaration of Helsinki; placebo orthodox vs. active-control orthodox.
4. Regulatory authorities/documents and placebo: placebo and national protection regulations; placebo and institutional ethics review boards; placebo and pharmaceutical companies; placebo and good clinical practice.

Submission and publication information

Please submit an abstract and your short bio (approx, 300 words each) to Prof. Miroslav Radenkovic by **31 June 2023**. Please email Professor Radenkovic at miroslav.radenkovic@med.bg.ac.rs and please CC artimon.teodora@uvvg.ro.

The authors of the accepted abstracts will be asked to submit their full papers by **16 October, 2023.**

This volume will be published in the "Bioethics and Medical Sciences" book series (ed. Miroslav Radenkovic) within the imprint **Ethics, Bioethics and Medical Sciences**, headed by Prof. Coralia Cotoraci, "Vasile Goldiș" Western University of Arad.