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Is the Gold Standard in Medical Clinical Trials Really Golden? An Opinion

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ABSTRACT

The randomized placebo-controlled peer-reviewed double-blind study: Randomized Controlled Trial (RCT) is the gold standard. Theoretically, this is correct. However, in reality, there are a number of false studies on the « marquet » in the scientific community. This is primarily due to human shortcomings, namely the investigator's dependence on their client and the client's financial interests. Billions in future sales are often at stake, whereas the physician receives a small salary and is dependent on subsidies from the initiator. It's also about the problem of "publish or perish." This article examines whether there are alternative ways to improve this unacceptable situation.

Keywords: Randomized Controlled Study, RCT, Gold Standard, Medical Clinical Trials.

INTRODUCTION

There is a gold standard for medical clinical trials, namely the randomized placebo-controlled peer-reviewed double-blind study: Randomized Controlled Trial (RCT) (1,2,3). Randomized means that participants are assigned to the treatment or control group at random in order to avoid bias. Controlled means that there are two groups, the verum group (receiving the new drug being evaluated) and the placebo group, which receives either a neutral drug or the previous standard treatment, in order to have a benchmark for testing the significance of the difference. Blinded means that it is either a simple blind, in which the subjects do not know what they are receiving, or—at a higher level—a double blind, in which neither the subjects nor the investigators know who is receiving what. This minimizes both subject bias (placebo effect) and observer bias. RCTs are considered the most reliable way to establish a cause-and-effect relationship between an intervention (e.g., a drug) and the outcome (e.g., improvement in parameters or even a cure). In a strict, often idealized sense, because they represent the highest scientific quality in terms of study design and implementation, they are referred to as gold standard studies.

THE REALITY

That is the theory, which unfortunately can differ from reality. Why? Financial interests can influence study results. This was published by Lopez-Moreno et al. (4), among others. Peer review of studies with differing results is best done through meta-analyses, as in this case. The study looked at the effect of red meat consumption on cardiovascular disease. It has often been suggested that this meat has a negative effect (e.g., on the development of colon cancer).

FUNDING, CONFLICTS OF INTEREST

In an analysis of 44 clinical studies, the authors found a clear correlation between funding and results. Two-thirds of the articles were directly or indirectly linked to the meat industry. All of

these studies came to neutral or positive conclusions about the effects of red meat consumption on blood lipid levels, blood pressure, or inflammation markers. Three-quarters of the independent, industry-free studies, on the other hand, found negative effects. The sticking point was usually the reference group. Industry-funded studies mostly chose a study design in which red meat was compared with other sources of animal protein or refined carbohydrates. Independent researchers, on the other hand, used plant proteins as a reference and came to significantly worse conclusions for red meat. The authors warn that biased study designs and conflicts of interest can systematically alter the results.

EXPERIENCES

The author of this article himself observed studies at university hospitals for many years. He came to the conclusion that, in addition, the final results were influenced during the course of the study by the fact that test subjects were eliminated from the study (reason: insufficient compliance), that undesirable outcomes were eliminated in the statistical evaluation (reason: outliers), and that some of the results were corrected by the study's funder in order to achieve significance. However, the researchers are dependent on funding from industry or foundations. If the study concerns a new drug, it should be noted that its development has often cost the manufacturing company many millions to billions of dollars/euros, so that an unfavorable study result would have enormous financial implications. In order to guarantee shareholder value, large manufacturers must have several new drugs in the pipeline that are expected to prove successful. Only new drugs can be patented, and generic drug manufacturers are already waiting to add new molecules to their portfolios. In any case, the drug's effectiveness in a large number of patients has been proven during the patent period.

NEGATIVE EXAMPLES

Let's look at a study conducted in China in 2016: An official review by the State Food and Drug Administration (SFDA) revealed that over 80% of the data from 1,622 clinical trials for new drugs was falsified or insufficient. Companies had concealed side effects, deleted data, or fabricated data—often due to economic pressure because local pharmaceutical companies had to compete with Western products (5).

Take the case of Dr. R. Fiddes in the United States in the 1990s. As head of the Southern California Research Institute, he recruited patients for dozens of studies by pharmaceutical companies – and was later charged with fabricating data and "ghosting" patients to simulate rapid recruitment. The study participants often existed only on paper, and dropout rates were kept artificially low (6).

Another example: Between 2013 and 2016, J. Palacio, a study coordinator at Unlimited Medical Research in Miami, falsified data for an asthma study involving children (7). She invented participants and manipulated results to deceive a pharmaceutical company. The study was supposed to test the safety and efficacy of a drug, but instead, false data ended up at the FDA.

Or take the scandal surrounding the Zain Clinical Research center in the US around 2016. A whistleblower, J. Bruinekool, revealed that blood samples had been mixed up, data falsified, and protocols manipulated for a study on a painkiller from Braeburn Pharmaceuticals (8). These examples are just the tip of the iceberg, as a Nature investigation from 2023 suggests: in some fields, up to a quarter of studies could be problematic or completely fabricated (9).

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Probably the most well-known scandal was that surrounding Merck's drug Vioxx (Rofecoxib) in 2000: the new "miracle cure" for arthritis pain that was supposed to cause less stomach bleeding than conventional NSAIDs. Merck earned $2.5 billion per year. But four years later, on September 30, 2004, Merck withdrew the drug from the market worldwide—after more than 88,000 heart attacks and 38,000 deaths associated with Vioxx (10).

NATURAL REMEDIES

Manufacturers of herbal medicines, homeopathic remedies, and natural remedies cannot patent their products and, in most cases, do not have the financial resources to conduct large clinical trials. They are then criticized for this by the regulatory authorities. They are therefore limited to studies that do not meet the gold standard. These are often anecdotal reports, which can be subjective and are therefore usually not recognized.

CONDITIONS

Of course, the gold standard is the goal, but the design must be truly double-blinded. Simple blinding opens the door to desired effects and abuse. The statistical evaluation must be carried out by independent experts without the influence of the study conductor. New drugs must have successfully passed all stages of testing before they can be approved.

Another issue concerns side effects and interactions. Clinical studies are designed in such a way that the number of test subjects ("time is money") is just sufficient to achieve significance. There are consistently fewer than a hundred. However, only the most important side effects appear. A large and further proportion of side effects and interactions only occur when a large number of patients take or are administered the drugs. It is a fact that the more effective the drug is, the greater the risk of side effects. This is particularly true for the new generations of drugs (antibodies, agonists, antagonists). If approval is granted too early, it is like conducting a field trial with the population as guinea pigs: an unacceptable situation.

AN ALTERNATIVE?

Doctors in Basel et al. have developed a new study design that enables fairer participation, better comparability, and more practical evidence (11). In the so-called "Random Invitation Single-Arm Trial" (RISAT), patients are randomly invited to participate in a study without a control group. Potential participants and their data are selected from existing registries, routine data, or patient records. Recruitment is quick and easy. This design combines the advantages of randomized studies with the use of routine data from everyday life. All that is needed is a high-quality electronic data infrastructure; AI can take care of the rest.

CONCLUSION

There is a wonderful theory regarding clinical trials, which unfortunately does not correspond to real-life experience (12). Those conducting studies are often not independent. The corruptibility of scientists through financial incentives or the withdrawal thereof is apparently a sign of the times. The sums involved are existentially crucial for all parties involved. What can be done? One could take the methodology out of the free market and thus remove the pressure to succeed and earn money. Studies could be conducted by specialized centers or foundations. In any case, a reform of the study system is necessary.

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