Commentary of "Placebo Studies in Developing Countries: Ethical, but not Ideal"

Eshikena, Marilyn

https://doi.org/10.7916/vib.v1i.6501

In his piece, Scott is against the notion that using placebos as controls (when there is an existing treatment method) in randomized controlled trials (RCTs) is never ethical. Using the four basic ethical principles, he supports why placebo trials in developing countries are not unethical. One common point that was raised throughout this piece is the fact that there is an additional player in clinical trials that affects the way we consider the ethicality of an RCT (especially in developing countries). This player is the exposure to medical treatment and care that would not have been otherwise available for an individual. In developing countries, this has a big part to play in beneficence of an RCT. An argument that Scott cites against placebo trials is the fact that subjects in the placebo arm are being deprived of the standard treatment method while they are in the study. For developing countries, however, in many cases, there is no existing standard of treatment for the disease being treated. Another area that Scott touches on is justifying placebo trials in developing countries for a disease that has a standard of care treatment in the developed world. While I agree with his point that the participants in this type of study are not exposed to any undue harm or deprived of any pre-existing treatment, it is still worth noting that these trials are not done entirely for the sake of their benefits. Drugs being tested in these countries are, many times, intended to also benefit members of the developed world. In a situation like this, I find it hard to justify how ethical it is to use placebo trials without thinking that there is a form of exploitation going on. Granted, according to the basic ethical principles, there is no wrong in these types of studies, but perhaps in addressing this subject, these four principles are not enough. It is for this reason that I suspect Scott titled his op-ed: “… ethical, but not ideal”.

One of the reasons why pharmaceutical companies carry out clinical trials in the developing world is because of the access to treatment-naïve potential subjects, as this population will probably make for better scientific results. Therefore, there is an additional advantage to be gained by using standard of care (as practiced in the developed world) controls in these trials. If there is no uncertainty as to the safety of using existing treatments on a population in a different environment for reasons of lifestyle or any other environmental factor, then it can be assumed that a drug that is beneficial to a patient in the U.S. will be beneficial to another patient in Laos, and vice versa.

Agreed, before a clinical trial is set up in the developed world, potential subjects may not have received any form of treatment. In fact, without these clinical trials, they may never be exposed to treatment for their disease. However, does it really sound ethical for us to play on this to justify placebo trials? Can we really say that clinical equipoise exists? The moment a clinical trial is set to run in the developed world, we can no longer play on the absence of treatment to confer advantages for us. We now owe subjects a responsibility and that is to provide them with treatment for their disease within the trial setting and outside the trial setting.