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EDITORIAL

The importance of clinical trial protocols

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The International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO) define a clinical trial as any research that prospectively assigns participants or groups of human subjects to one or more interventions (medicines, procedures, devices, behavioral treatments, dietary supplements and diets, for example). These trials aim to evaluate the effects of interventions on human health[1].

Prospective clinical research is essential for discovering new knowledge, improving the scientific base, solving challenges, and improving clinical practices. The basic principles for a successful researcher include interest, availability, persistence, and honesty. However, it is essential that, first of all, one has complete and detailed knowledge of scientific writing and preparation of the research protocol[2].

A complete clinical research protocol must include the fundamentals of the topic, the existing scientific gap, the specific question to be answered, the primary and secondary objectives, the methodology (design, description of variables, sample size, randomization, allocation, criteria inclusion and exclusion, intervention, efficacy and safety parameters and statistical analysis), a free and informed consent form, a clinical record, and references. Approval from the Research Ethics Committee and declaration of financing are essential[2].

Although clinical trials have been conducted for many years, it was only recently, more precisely in 2004, that the ICMJE[1] recommended registering their protocols. The objectives of protocol registration are 1) to prevent selective publication of reports and partial reporting of research results, 2) to avoid unnecessary duplication of research, 3) to help patients and the public know what trials are planned or ongoing to which they may wish to subscribe, 4) to assist research ethics committees in evaluating new studies by providing insight into the work and data relevant to similar research being considered, and 5) to provide a platform for reading, updating, and closing the research stages.

The guidelines for writing randomized clinical trials (CONSORT[3]) and research protocols (SPIRIT[4]) define the need to cite the protocol registration in their subitems. Therefore, most reputable medical journals do not accept clinical trial submissions without proper registration.

Created in December 2010 by the Brazilian government, the Brazilian Clinical Trials Registry (Rebec[5]) is a joint project of the Ministry of Health (Decit/MS), Pan American Health Organization (Opas), Latin American and Caribbean Center for Health Sciences Information (Bireme), and Ibict/Fiocruz, which currently manages Rebec. It is the national platform for registering studies since the insertion of national studies on foreign platforms is currently limited.

The WHO Registry Network comprises the Australian New Zealand Clinical Trials Registry (ANZCTR), the Chinese Clinical Trial Registry (ChiCTR), the Clinical Research Information Service (CRiS) of the Republic of Korea, the Clinical Trials Registry - India (CTRI), the Cuban Public Registry of Clinical Trials (RPCEC), the German Clinical Trials Register (DRKS), the Iranian Registry of Clinical Trials (IRCT), the International Standard Randomized Controlled Trial Number (ISRCTN.org), the Japan Primary Registries Network (JPRN), the Netherlands National Trial Register (NTR), the Pan African Clinical Trial Registry (PACTR), the Sri Lanka Clinical Trials Registry (SLCTR), and Rebec. ClinicalTrials.gov is one of the largest platforms in existence and is managed by the National Library of Medicine and the National Institutes of Health.

A clinical trial without a pre-published protocol and proper registration would not make its execution unfeasible, but it would reduce the credibility of its execution and published data. Researchers must be aware that basic and simple clinical trials, without millionaire industry support, generally lack these fundamental steps. Journal editors and reviewers must ensure the quality of experimental clinical work submitted for publication by checking their protocols and records on their respective platforms. The scientific community that evaluates published literature, in turn, must always be vigilant in detecting publication failures and inconsistencies between the original protocol and its final work.

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