SCIENTIFIC ARCHIVES OF DENTAL SCIENCES

Volume 2 Issue 2 February 2019

Editorial

Clinical Research: From Observational to Clinical Controlled Trial Studies

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Received: December 06, 2018; **Published**: December 31, 2018

Nowadays, there is a tendency to generate research based on the review of the literature and its statistical analysis. Systematic reviews and meta-analyzes have an increasing prominence and clinical studies, whether observational or randomized controlled studies, are losing notoriety. One of the possible factors involved in this situation may be the obstacles experienced by the researchers derivated from the ethics committees of the different countries and, on the other hand, by the resources required to generate a good research. If this tendency is maintained, will be a lack of information based on real clinical studies. The clinical studies permit the development of the research, especially in the searching of diagnostic methods and in the management of illness in the medical and odontological specialties.

Well-designed clinical trials are a useful tool if they allow to infer valid results and conclusions to be drawn. The good design of them is based on generating a methodology that include a series of aspects to eliminate all risk of bias, from the selection of the subjects or the patients to the expression of the results and the statistical analysis of them. If a rigorous methodology is followed, even though the clinical study is not a randomized clinical trial with blinding of subjects, researchers and statisticians, the results can be useful in demonstrating causality. Good clinical studies might contribute and be part of globalized studies such as systematic reviews.

The quality of the evidence derived from a clinical study reflects the reliability of the effects of its results. Obviously, a design of a randomized controlled clinical trial allows to produce a great confidence if they evidence a high quality without limitations and risk of bias. This is because both, the selection and the distribution of the sample are carried out in a randomized manner and the methodology and measurement instruments used are adequate. However, observational clinical studies, if rigorous and controlled, can provide strong evidence that allows valid conclusions to be drawn. These non-randomized clinical trials (also called quasi-randomized clinical trials) start with a risk of bias due to the lack of random selection of the sample; however, their rigorousness can allow them to obtain a high quality of evidence.

For the development of clinical studies, ethical and economic factors will generate difficulties that often threaten the execution of them.

With respect to ethical factors, it is important to express that all studies should be governed by the Helsinki declaration. In this document there is a topic of great importance when a project is generated: "The purpose of the clinical investigation in human beings is to understand the causes, evolution and effects of the diseases and to improve the preventive, diagnostic and therapeutic interventions". But to achieve this, it must be following up a series of ethical standards that are declared one by one. However, next to this statement, there are the standards of the ethics committees of the different responsible entities in each of the countries. Unfortunately, many of them have visions that go out of the context of the Declaration of Helsinki and many times they watch more for their own interests than for the progress of the investigation. The economic factor is still important when generating clinical research projects. Undoubtedly, clinical studies involving high-cost assessment instruments, such as the use of magnetic resonance, means that many of the projects can not be carried out.

Despite the complications with which the research clinician may find, it is important to reformulate each of the research ideas as: a) they comply with the Declaration of Helsinki; b) look for the best way to generate projects that have the possibility of being developed; and c) follow the guidelines and regulations given by the groups that provide the conditions to determine risks of bias and quality of the information.

I would like to end this communication by reminding readers that the first clinical investigation that allowed a great development was performed by Lind in 1753, about scurvy. Despite having carried out his research in 12 subjects, he was able to control the variables although he did not include a control group. While there was already a primitive design generated in the ninth century to apply some trials, this did not evolve until the nineteenth cen-

tury when the concept of double blind was introduced and later in the twentieth century when the concept of placebo was included. These simple studies, conducted so many years ago, show a great advance in research and allowed to lay foundations so, today we can conduct clinical research that meets the best standards in order to search for causes, generate programs and above all, consider and take care of the subjects involved in the sample.

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