MEDwave

Letters to the editor
Medwave 2015 Nov;15(10):e6313 doi: 10.5867/medwave.2015.10.6313

About clinical trials: methodological and bioethical considerations

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Citation: Alva Díaz C, Aguirre Quispe W. About clinical trials: methodological and bioethical considerations. *Medwave* 2015 Nov;15(10):e6313 doi: 10.5867/medwave.2015.10.6313
Publication date: 13/11/2015

Dear editor:

The editorial published in September 2015 (doi: 10.5867/medwave.2015.08.6273) addresses some methodological aspects and bioethical considerations in the conduct of clinical trials (CT), highlighting relevant aspects of design, reporting and publication, compliance with good clinical practices (GCP) and quality through the CONSORT instrument. In this regard, we make some considerations:

- Clinical trials have variable duration, only the clinical phase may last from 6 to 11 years, and considering pre-clinical and approval phases could reach 19 years. Regarding costs, the average of the clinical phase is $ 125 million and the probability of approval for the use of a new molecule is 8%. Therefore is relative the claim that clinical trials are the fastest way, despite being efficacy studies they are not always the most efficient in time and cost [1].
- Clinical trials solve problems related to interventions (preventive, therapeutic or diagnostic) but other questions about health, clinical trials may not answer, for ethical, methodological or economic issues, and that are relevant to decision-making using other research designs: epidemiological profiles, burden of disease studies, cost-effectiveness studies, and diagnostic tests, among others. Therefore, a clinical trial is not always the fastest and most effective way to develop scientific knowledge.
- Clinical trials about tests and diagnostic techniques exist; their use is becoming more common and are carried out under the design of a clinical trial, and can even be requested by international regulators such as FDA or EMA to determine the validity thereof [2]. Therefore, a clinical trial is not only used in research to evaluate therapeutic or preventive interventions, also in diagnostic interventions.
- In clinical trials, the use of the principle of intention to treat decreases attrition bias and is a Good Clinical Practice (GPP) consideration. We therefore affirm the need and recognize the importance of this type of analysis [3].
- Conducting clinical trials, despite the greater proportion is done by the pharmaceutical industry (in Peru over 90% [4]), is a public health need. Therefore it is necessary that populations of Latin American countries participate for different reasons:

    1. To assure safety evaluation of pharmacological interventions that are different due to genetic variability and allow for subgroup analysis to assess their potential effectiveness in our populations.
    2. To create scenarios with the highest standards required by Good Clinical Practice and ethical standards for conducting the trials.
    3. To consider the potential benefits of new drugs for diseases of our population in which the epidemiological profile and disease burden is composed of both infectious and chronic diseases.
    4. To train local researchers in scientific and bioethical methodologies for conducting research on human beings.

All of this with the requirement of respect for human rights, state regulation and institutions to ensure the defense of the rights of patients who participate in clinical trials.

Notes

From the editor
This article was originally submitted in Spanish and was translated into English by the authors. The *Journal*has not copyedited this version.

Conflicts of interest
The authors declare no conflict of interest with the issue addressed in the letter.

Funding
The authors declare not having received funds for the completion of this work.

References

1. The Drug Development and Approval Procces. fdareview.org [on line] | Link |
2. U.S. National Institutes of Health. ClinicalTrials.gov. [on line]. | Link |
3. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. The Cochrane Collaboration, 2011. [on line]. | Link |
4. Minaya G, Fuentes D, Obregón C, Ayala-Quintanilla B, Yagui M. [Characteristics of clinical trials authorized in Peru: 1995-2012]. Rev Peru Med Exp Salud Publica. 2012 Oct-Dec;29(4):431-6. | CrossRef |

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