

Letters to the editor

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Clinical trials in Latin American countries

Authors: José Kelvin Galvez-Olortegui[1,2,3,4], Tomas Vladimir Galvez-Olortegui[1,3,5], Yudy Cley Córdor-Rojas[3,6]

Affiliation:

[1] Facultad de Medicina, Universidad Nacional de Trujillo, Trujillo, Perú

[2] Comité Permanente de Investigación, Facultad de Medicina, Universidad Nacional de Trujillo, Trujillo, Perú

[3] Scientia Clinical and Epidemiological Research Institute, Trujillo, Perú

[4] G.A.C. N° 116, Centro Médico 32° Brigada de Infantería, Ejército del Perú, Trujillo, Perú

[5] Instituto Regional de Oftalmología, La Libertad, Trujillo, Perú

[6] Escuela de Posgrado, Universidad Privada Antenor Orrego, Trujillo, Perú

E-mail: jgalvezo@scientiaceri.com

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Dear editor:

The editorial published on September 2015 (doi: [10.5867/medwave.2015.08.6273](https://doi.org/10.5867/medwave.2015.08.6273)) addresses characteristics of clinical trials, highlighting the relevant issues about their design, report and publication, meeting good clinical practice and quality using the CONSORT tool.

The development of clinical trials in developing countries has increased proportionally to the technology, globalization, expertise and training of researchers. We propose some issues to take into account.

Are clinical trials necessary in developing countries?

Some authors advocate their necessity, due to the epidemiological differences between developed and developing countries, being chronic and infectious diseases the most frequent, respectively [1]. Most clinical trials in Peru [2] and Latin America are sponsored by the pharmaceutical industry [3], and are targeted to solve the public health problems of developed countries. In this context, developing countries will receive drugs tested in their population, at high prices and with long patents (Trans-Pacific Partnership Agreement), which will affect the access and health care in our region.

Is voluntary consent to enroll in clinical trials guaranteed, when alternative treatment options are lacking?

Participation in clinical trials is influenced by the poverty level, education, access to health services, etcetera; so that in many Latin American countries, clinical trials have taken place in populations with no access to adequate health services [4]. Therefore, many patients were compelled to being recruited for clinical trials, being the only possibility

to access (randomly) to a treatment not available in a non-participation status.

Are there efficient programs and policies that support the design and conduction of clinical trials in developing countries?

There are isolated efforts of some Latin American countries and the Pan American Health Organization, targeted to promote epidemiological studies through policies and programs of research, development and innovation in healthcare [5]. However, these are not sufficient and we have to understand that there are complex issues of individual and public health in our region, solvable through clinical trials classified as pragmatic, cluster and community based. These methodological issues, the failure to identify knowledge gaps pending to address and the weakness of the research systems, are challenges that we still have to face in order to contribute to the development of the health of our countries.

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 interests

The authors declare not having any conflict of interests with the matter dealt with in this letter.

References

1. Yusuf S. Clinical research and trials in developing countries. *Stat Med*. 2002 Oct 15;21(19):2859-67. | [PubMed](#) |

2. 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. | [PubMed](#) |
3. Reveiz L, Sangalang S, Glujovsky D, Pinzon CE, Asenjo Lobos C, Cortes M, et al. Characteristics of randomized trials published in Latin America and the Caribbean according to funding source. PLoS One. 2013;8(2):e56410. | [CrossRef](#) | [PubMed](#) |
4. Angell M. Investigators' responsibilities for human subjects in developing countries. N Engl J Med. 2000 Mar 30;342(13):967-9. | [PubMed](#) |
5. Reveiz L, Elias V, Terry RF, Alger J, Becerra-Posada F. Comparison of national health research priority-setting methods and characteristics in Latin America and the Caribbean, 2002-2012. Rev Panam Salud Publica. 2013 Jul;34(1):1-13. | [PubMed](#) |

Author address:

[1] Scientia Clinical and Epidemiological Research
 Institute
 Mz. G Lt. 22
 Urb. Vista Hermosa
 Trujillo
 Perú



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