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1. Registration of clinical trials

Clinical trials are among the best evidence for clinical decision making. To be considered a clinical trial a research project must involve patients and be prospective. Such patients must be subjected to clinical or drug intervention with the purpose of comparing cause and effect between the groups under study and, potentially, the intervention should somehow exert an impact on the health of those involved.

According to the World Health Organization (WHO), clinical trials and randomized controlled clinical trials should be reported and registered in advance.

Registration of these trials has been proposed in order to (a) identify all clinical trials underway and their results, since not all are published in scientific journals; (b) preserve the health of individuals who join the study as patients and (c) boost communication and cooperation between research institutions and other stakeholders from society at large interested in a particular subject. Additionally, registration helps to expose the gaps in existing knowledge in different areas as well as disclose the trends and experts in a given field of study.

In acknowledging the importance of these initiatives and so that Latin American and Caribbean journals may comply with international recommendations and standards, BIREME recommends that the editors of scientific health journals indexed in the Scientific Electronic Library Online (SciELO) and LILACS (Latin American and Caribbean Center on Health Sciences) make public these requirements and their context. Similarly to MEDLINE, specific fields have been included in LILACS and SciELO for clinical trial registration numbers of articles published in health journals.

At the same time, the International Committee of Medical Journal Editors (ICMJE) has suggested that editors of scientific journals require authors to produce a registration number at the time of paper submission. Registration of clinical trials can be performed in one of the Clinical Trial Registers validated by WHO and ICMJE whose addresses are available at the ICMJE website. To be validated, the Clinical Trial Registers must follow a set of criteria established by WHO.

2. Portal for promoting and registering clinical trials

With the purpose of providing greater visibility to validated Clinical Trial Registers, WHO launched its Clinical Trial Search Portal (http://www.who.int/ictrp/network/en/index.html), an interface that allows simultaneous searches in a number of databases. Searches on this portal can be carried out by entering words, clinical trial titles or identification number. The results show all existing clinical trials at different stages of implementation with links to their full description in the respective Primary Clinical Trials Register.

The quality of information available on this portal is guaranteed by the producers of the Clinical Trial Registers that form part of the network recently established by WHO, i.e., WHO Network of Collaborating Clinical Trial Registers. This network will enable interaction between the producers of the Clinical Trial Registers to define the best practices and quality control. Primary registration of clinical trials can be performed at the following websites: www.actr.org.au (Australian Clinical Trials Registry), www.clinicaltrials.gov and http://isrctn.org (International Standard Randomized Controlled Trial Number Register (ISRCTN). The creation of national registers is underway and, as far as possible, registered clinical trials will be forwarded to those recommended by WHO.

WHO proposes that as a minimum requirement the following information be registered for each trial. A unique identification number, date of trial registration, secondary identities, sources of funding and material support, the main sponsor, other sponsors, contact for public queries, contact for scientific queries, public title of the study, scientific title, countries of recruitment, health problems studied, interventions, inclusion and exclusion criteria, study type, date of the first volunteer recruitment, sample size goal, recruitment status and primary and secondary result measurements.

Currently, the Network of Collaborating Registers is organized in three categories:

» Primary Registers: Comply with the minimum requirements and contribute to the portal;

» Partner Registers: Comply with the minimum requirements but forward their data to the Portal only through a partnership with one of the Primary Registers;

» Potential Registers: Currently under validation by the Portal's Secretariat; do not as yet contribute to the Portal.

3. Dental Press Journal of Orthodontics - Statement and Notice

DENTAL PRESS JOURNAL OF ORTHODONTICS endorses the policies for clinical trial registration enforced by the World Health Organization - WHO (http://www.who.int/ictrp/en/) and the International Committee of Medical Journal Editors - ICMJE (# http://www.wame.org/wamestmt.htm#trialreg and http://www.icmje.org/clin_trialup.htm), recognizing the importance of these initiatives for the registration and international dissemination of information on international clinical trials on an open access basis. Thus, following the guidelines laid down by BIREME / PAHO / WHO for indexing journals in LILACS and SciELO, DENTAL PRESS JOURNAL OF ORTHODONTICS will only accept for publication articles on clinical research that have received an identification number from one of the Clinical Trial Registers, validated according to the criteria established by WHO and ICMJE, whose addresses are available at the ICMJE website http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/. The identification number must be informed at the end of the abstract.

Consequently, authors are hereby recommended to register their clinical trials prior to trial implementation.

Yours sincerely,

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