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Study of Ethical Standards in Clinical Trial Research on Children

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ABSTRACT: Scientific studies have developed medical science field and consequently have left positive effects on promoting level of health and reduction of diseases in humans; study of the ethical considerations in clinical trial research on children is a very sensitive and important issue that deserves attention. The present paper discusses this issue in the clinical trial research on children. Fifty articles published on Scientific Information Database of Jahad Daneshgahi, encompassing the report of clinical trial research on children, were studied in terms of observance or nonobservance of the ethical codes (five ethical codes). The purposive sampling method was used to select the studies. According to the analysis, 40 items (80 percent), 4 items (8 percent), 6 items (12 percent), 23 items (46 percent) and all of them (100 percent) observed the ethical codes of one, two, three, four and five, respectively. Among the studied articles, one paper observed all the five ethical codes. With respect to the importance of ethical considerations, scientific journals and publications should pay more attention and inform authors of observing these considerations.

Keywords: Ethical Standards, Children, Clinical Trial

ORIGINAL ARTICLE

INTRODUCTION

Along with the advances in medical researches, ethical issues are also considered and raise more ethical issues (Shadi, 2006). Thus, for the observance of ethical issues in medical research some guidelines such as declaration of Helsinki as a statement of ethical principles for medical research have been developed (Farhadi et al., 2004). Evidences have been shown that lack of attention to ethical issues cause serious harm to participants is medical research (Weindling, 2005; Larijani, 2004). In Iran some efforts to develop ethical guidelines for medical research has been done (Khodaparast et al., 2007). Some studies in the field of medical research are conducted by the clinical trial method. The clinical trial studies are essential and should be carried out to promote welfare, treatment, prevention and diagnosis of diseases in adults and children (Piantadosi, 1997). However, this necessity does not hinder us from ignoring ethical considerations in these studies. Some of the clinical trial studies are conducted on children. Children, as the sample under study in these studies, are developmentally, physiologically and psychologically different from adults. This issue, on the one hand, underlines the importance of the ethical standards in these studies and on the other hand, the ethical principles and standards are required, which are different from the studies carried out on adults (Gill, 2004).

Clinical trial is one of the types of the medical studies, which is conducted on human populations. The Important application of clinical trials is in studying the effects of medicines and new treatment methods. A clinical trial for a pharmaceutical product is performed on humans when convincing information is collected on the quality of this product and its non-clinical safety and confirmation of health authority or Research Ethics Committee is gained in the country where the research has been conducted. Clinical trial is usually performed in two forms of preclinical studies and clinical studies. In preclinical studies, cells, tissues and animals are studied, whereas, in clinical studies, the research is mainly performed on human participants (Goetghebeur et al., 1998).

An independent committee of physicians and statistics specialists supervises the process of clinical trials confirmation. This committee should be confident of the risks of the pertinent clinical trial are low and its potential advantages are valuable. Yet, a considerable amount of the clinical trial studies, especially on children, does not observe such standards and if they do, they do not include this issue in their research report. By studying some of the clinical trials research on children, the present research reviews observance of the ethical standards. Based on this, the present research aims to discuss observance of the ethical standards in clinical trial studies on children.

METHODS AND MATERIALS

The present research was conducted through observational description method and reviewing documents. The statistical population of the present research is the research articles, which prepared through

clinical trials on the population of children in Iran between 2003 and 2011 and its report was published as a full-text scientific-research article on Scientific Information Database (SID) (Iranian database of research articles, 2003-2011). Purposive sampling method was used to select the articles. After sampling, 50 articles were selected for the final analysis. "References" of the present paper provide the specifications of the analyzed articles. The selected articles were reviewed in terms of observing five items of the ethical standards of children clinical trial, which are as follows:

- Gaining free and informed written consent from parents of children (Code 1)
- Providing a child with the necessary information with respect to his/her level of understanding and ability and attracting child's attention for cooperation (Code 2)
- The charges imposed on the participants should be borne by the researcher (Code 3)
- Answering the questions and concerns of portents during the research (Code 4)
- Maintaining confidentiality (Code 5)

Frequency and percentage descriptive statistics were used to analyze the collected data.

RESULTS

As mentioned in "Materials and Methods" section, 50 scientific-research articles discussing clinical trial on children were reviewed. Table 1 shows number of the articles during 2005-2011.

Table 1. Frequency and percentage of articles published per year

Row	Year publication	Frequency	Percentage
1	2003	2	4
2	2004	4	8
3	2005	6	12
3	2006	16	32
4	2007	9	18
5	2010	9	18
6	2011	4	8

Table 2: Frequency and percentage of articles published per Code Number

Row	Code Number	Frequency	Percentage
1	One	40	80
2	Two	4	8
3	Three	6	12
4	Four	23	46
5	Five	50	100

As table 1 shows, the maximum and the minimum number of the reviewed articles are related to 2006 (32 percent) and 2003(4 percent). All of the abovementioned articles were assessed with respect to the five ethical codes mentioned in "Materials and Methods" section. According to the analysis, 40 items (80 percent) of the published articles observed ethical Code No one, 4 items (8 percent) observed ethical Code No two, 6 items (12 percent) observed ethical Code No three, 23 items (46 percent) observed ethical Code No four, and all items (100 percent) observed ethical Code No five. One of the reviewed articles observed all the five ethical codes. Table 2 shows the results in detail.

According to table 2, the maximum and the minimum percentages of observing ethical code are related to the ethical Code No one (80 percent) and Code No two (8 percent), respectively.

DISCUSSION

One of the remarkable issues in clinical trial studies on children is observance of ethical standards. The present research was carried out aiming to study observance of the ethical standards in these studies. According to the findings, only one study observed all pertinent codes of ethical standard. An overview on the findings shows that the majority the studies did not observe the ethical codes, whereas the ethical codes No 1 and 5 were observed in most studies. Ethical Code No 3 was observed by approximately half of the studies. Ethical Code No 2 discusses that children should be involved in making decisions on their health and improvement; children are provided with the necessary information with respect to their level of understanding and abilities and they are required to express their ideas on cooperation. One of the possible reasons for non-observance of this standard could be lack of information of the researchers on this ethical standard. Ethical code No 3 is about the charges imposed on participants, which should be paid by the researcher. Non-observance of this standard may be due to the tendency of researchers to use the patients hospitalized in the hospitals of their own surgery as the research samples. Ethical codes No 1 and 5 are about the free and informed written consent from parents of a child and maintaining confidentiality and a high percentage of the studies observed the necessary standards. Ethical Code No 4 is on answering the questions and concerns of parents during a research. According to this ethical code, parents of the children who participate in a research have the right to ask questions about the process of a study and express their concerns. Here, about half of the reviewed studies did not observe this code.

Generally, the findings of the present research show that some of the ethical codes were neglected in the clinical trial studies. Such negligence may be due to non-

observance of the pertinent ethical code and/or because of excluding that in the report of the study. Meanwhile, scientific-research journals and publications, especially reviewers of journals should pay more attention when studying the received manuscripts. In case the manuscripts sent to journals did not observe the required ethical standards, they should avoid accepting and publishing them. Alternatively, scientific-research journals, seminars and scientific centers should be more active in making researchers and authors acquainted with the ethical standards.

The findings of the present research had some limitations, which should be considered and removed in the following studies. One of the limitations is related to the way manuscripts are selected for analysis. Using the purposive sampling method may lead to bias in selecting articles, It is recommended to use the random sampling methods in the future studies. The present research only studied the articles published on Scientific Information Database of Jahad Daneshgahi, especially during a certain period. It is recommended to study the articles published in other domestic and foreign scientific databases for future research**.**

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