THE STUDY OF THE TRIAL SUBJECTS' PROTECTION ASPECTS DURING ORGANIZING AND HOLDING CLINICAL TRIALS IN UKRAINE

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Introduction. The start of any clinical trial (CT) is impossible without its approval by the research ethics committee (REC). Our analysis of literature sources showed that the world's great attention is paid to assessing and improving the quality and efficiency of the RECs work. In Ukraine there are about 500 local research ethics committees (RECs) that perform the review of different health research projects including clinical trials of drugs and medical devices. As for today their work isn't studied enough. There is a need to develop tools to assess the quality and effectiveness of the RECs work. The lack of supervision and coordination of local RECs activity, patchy and incomplete guidelines for the RECs hinders effective protection of human subjects.

The aim of this work is to find strengths and weaknesses of the REC system in Ukraine and to identify challenges to the effective functioning of the REC system in Ukraine for increasing the trial subjects' protection.

Materials and methods. The interview of the RECs' members was held to evaluate the accordance of the RECs to the regulatory requirements. The questionnaire for respondents consisted of two parts and contained questions about RECs' work organizing, membership and members' educational training.

The results. The analysis of the obtained results showed that most of the RECs (60.9%) are functioning 6 – 10 years. 100% of RECs use national regulations in their work; 95.7% use GCP, 65.2% - declaration of Helsinki, 26% - Oviedo convention and 21.7% - Nuremberg code. This shows not enough awareness of RECs in international regulations in CT. 17.4 % of RECs don't use their policy in work what contradicts with the regulatory requirements and could lead to decreasing of the trial subjects' protection. At 26% of RECs the head and at 78.3% - members of RECs were assigned by the healthcare institutions administration where the RECs are functioning. This could be the reason for possible conflict of interests during ethical review of the CT since on this fact shows the dependence of the RECs from the healthcare institutions administrations but RECs should be independent during the review of CT. More than 60% of RECs have need in development of different kind of documents for improvement the effectiveness of the REC's work.

Conclusions. The obtained results showed the need of farther research on RECs' work to increase the trial subjects' protection during organizing and holding CT in Ukraine.