CLINICAL TRIALS IN CORONAVIRUS PANDEMIC: THE PERSPECTIVE ON HUMAN SUBJECTS PROTECTION

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Introduction. The unfavorable epidemic situation, caused by the spread of coronavirus, has created numerous obstacles both for the usual processes of planning and conducting clinical trials (CT) and for assessing their ethical and morally-legal aspects. Obviously, that in the conditions of pandemic there are additional risks for the research subjects, that requires deeper ethical analysis and monitoring of both the researches related to treatment and prophylaxis of COVID - 19, and CT, that were started before pandemic. The results of such an analysis are necessary to create a methodological basis for the development of new requirements and practical recommendations for the routine process of ethical assessment of CT and monitoring the protection of rights and safety of both subjects and research personnel.

Aim. The aim of this work is to analyze the influence of coronavirus pandemic on the protection of rights, safety and well-being of patients in CT. The following tasks were intended to resolve: to identify the factors caused by the pandemic that affect the risk / benefit ratio in CT, to consider their possible negative consequences and to identify key ethical aspects of CT which are held out during a negative epidemic situation.

Materials and methods. method of theoretical analysis, logical method, abstractions.

Results and discussion. An analysis of influence is pandemic in CT, which is not related to COVID-19, allowed to detect additional risks for patients, due to quarantine restrictions and the threat of infecting of COVID-19 as a result of the increased number of contacts. At the same time, the remote distance forms of CT, including receipt informed consent and patient safety monitoring on the one hand protects patients from the risk of infection COVID-19, and on the other hand can negatively affect of the quality of the patient's condition, the possibility to communicate with the investigator, timeliness of response to the adverse reactions and adverse events. As a result of the temporal termination of CT under conditions of pandemic patients can remain without access to the treatment that is especially undesirable, if a patient gets considerable therapeutic benefit and/or the alternative equivalent methods of treatment outside the CT are not available. Temporary termination of CT results can have negative consequences to patients because this results in violation of rights for patients on access to participating in CT, especially if it involves separate vulnerable categories. Clinical trials which are dedicated to treatment or prophylaxis of COVID-19, also associated with additional risks, that first of all consist in possible harm due to low efficiency of the investigated interference, and high level of uncertainty through insufficiency of scientific knowledge in relation to a coronovirus infection. On the other hand, such trials are vitally necessary for the separate categories of patients, which will receive the only chance of direct therapeutic benefit, and are extremely important for all society.

Conclusions. So, conducting ethical analysis of CT given new context of the pandemic is significantly complicated, but is extraordinarily a necessity for the proper justification of continuation or termination of CT, the initiation of new trials, but most importantly - ensure proper assessment of risks and benefits to the individual patient. The development of general methodology for conducting such analysis in the conditions of pandemic is important, which will be laid in the basis of practical recommendations conducting an assessment of ethical and morally-legal aspects of clinical trials, which conducting during a pandemic. of society and scientific progress in a fight against a pandemic.