ASSESSMENT OF QUALITY OF LIFE IN HEALTHY VOLUNTEERS WHO PARTICIPATE IN CLINICAL TRIALS

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In many areas of medicine there is used the concept of quality of life which is a health-related issue. Assessment of the patient's quality of life includes physical, psychological, social, economic, and spiritual aspects of his life. Improving the quality of life is either a main or an additional goal of any treatment. The criteria of treatment efficacy in clinical studies take into account the physical findings and laboratory data. At the same time the studies of quality of life are held in many areas of medicine, particularly in palliative medicine, cardiology, oncology, psychiatry, endocrinology, neurology and others. The main areas of such research include the standardization of methods of treatment, examination of new methods of treatment and medicines, the development of predictive models of disease and economic feasibility methods of treatment.

In certain diseases volunteer's assessment of his condition is the most important indicator of health. The 36 – item short form of the Medical Outcomes Study questionnaire (SF-36) was designed as a generic indicator of health status for use in population surveys and evaluative studies of health policy. It was set to assess the quality of life of the patient, widely used in the clinical trials. It is widespread in Europe and in the USA, it can also be used in conjuction with disease-specific measures as an outcome measure in clinical practice and research. According to the study protocol requirements we have experienced the use of this questionnaire in patients with rheumatoid arthritis. We consider that it is necessary to submit the quality of life surveys to healthy volunteers as well. We have developed the special questionnaire which is based on the approved quality of life surveys and covers 10 questions about physical functioning, general health, vitality, social functioning, emotional state, mental health. Within the quality assurance procedures we have introduced this questionnaire to the healthy volunteers who took part in the bioequivalence studies which are run in the Clinical and Diagnostics Center of the National University of Pharmacy. The time range was specifically calculated according to the standard schedule of bioequivalence study and it may describe how the volunteers' quality of life has changed during the trial. We think that the developed quality of life questionnaire will reflect the special aspects of the general well-being and health of the participants of the clinical study. This information will represent the comprehensive approach to the quality assurance of the given study.