PROBLEMS OF CLINICAL TRIALS OF CHILDREN'S MEDICINES

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According to WHO data, 5 million children annually die because of lack of adequate children's medicines. The reason of such deficiency is that long time the child was perceived by medicine as the adult in a miniature. But at the international level it is proved: the children's organism has a number of features which need to be considered at purpose of preparations. Immaturity of bodies and systems, features of a metabolism of the child can influence pharmacokinetics of medicines and, finally, efficiency of therapy.

Shortage of children's medicines is a global problem; it has the negative influence on developing countries. Around the world, the most part of drugs is used incorrectly, that is influence of these preparations is properly not studied, preparations have no license for application.

There isn't a lot of drugs having specially developed structure. Existing medicines, which have such a composition can not be applied for children. About three million children till 5 years, every year die of pneumonia and diarrhea. Reliable treatment of diarrhea happens to use of zinc and salt which is necessary for an oral regidratation. At the same time, supervision say that such treatment can't often be carried out in clinics where diarrhea is widespread. Increase of access to such drugs in drugstores, will save millions of lives.

If drugs which are developed for children are inaccessible, then parents and workers of health care quite often apply parts of adult doses, or crush tablets or capsules to dissolve them in water. Such practice is difficult, reception of a preparation can cause difficulties in the child, and it leads or to overdose of a preparation, or to his insufficient dosage. All this leads, as a result, to collateral manifestations or to inefficient treatment.

In the USA specialists of medical university of the Duke and National institute of health with assistance of FDA have checked 300 pediatric preparations. It has turned out that 122 of them demand completion in connection with toxicity or lack of efficiency from children.

The subcommittee of the European Union on social problems and affairs of consumers found out how qualitative and effective drugs are on sale in the countries of Europe. It is established that 90% of drugs for newborns and a half of drugs for children of more advanced age by production don't pass full clinical tests in the relevant age groups.

Carrying out a full cycle of clinical tests is rather long and difficult procedure, which except big financial expenses, is connected also with a number of ethical and technological problems. Besides, clinical tests have to be carried out separately for each age group. Therefore, many companies save time and money and refuse a full cycle of clinical tests, being limited to only minimum necessary researches.

To solve this problem at the European agency on regulation of medical supplies the special working group on research of children's drugs has been created. The group has conducted full clinical trials of the most popular and widely used medicines.

The first results have shown that Ibuprofen, which is often used as febrifugal, and an anesthetic for children there has successfully passed all cycle of tests and is quite safe preparation. Further experts plan to test such preparations as Analgene, Paracetamol and Aspirin, which are made by the largest companies of the countries of Europe.

The market of children's preparations the huge market window, but is necessary for his development obligatory intervention of the state.