Clinical drug trials

Clinical trials of new drugs are classically divided into three phases.

First stage

In the first phase (20-100 patients), the safety of the used substance, its pharmacokinetics and pharmacodynamics, and the appropriate dosage for further tests are verified.

Second stage

In the second phase of clinical trials (20-300 patients), in which a new drug usually proceeds only after it has been established that it is sufficiently safe, its ability to achieve the desired effect against the given disease is verified in particular. Of course, all unwanted side effects are still being monitored. If the new drug is effective enough, it advances to the third phase.

Third stage

The third phase of clinical trials (300-3000 or more patients), which is the most expensive, longest and most demanding. These are randomized, multicenter studies, the goal of which is to determine whether a new drug (or its combination with other drugs) is more effective against a given disease than the current golden standard of treatment. It is only on the basis of the results of the third phase of clinical tests that a new drug is approved for the treatment of a given disease in normal clinical practice. However, the third phase can take place for various combinations of the given drug with other drugs even after its approval for routine clinical treatment, for example, currently 24 VELCADE® clinical trials in the third phase, all against multiple myeloma, can be found on the NCI website. The cost of clinical trials for a single new drug from the beginning of the first phase of testing to its introduction into routine clinical care is estimated [1] at half a billion USD ($1 in 2000 value).

Fourth stage

However, due to significant variability in the human population, the safety and effectiveness of the drug must be monitored even during its normal use, which is often referred to as the fourth phase of clinical trials. Recently, it has been suggested that [2] any unexpected positive effects of the given drug on other diseases that the patient suffers from at the same time should also be monitored during this phase.

Links

References

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2. BOGUSKI, Mark S – MANDL, Kenneth D – SUKHATME, Vikas P. Drug discovery. Repurposing with a difference. *Science* [online]. 2009, vol. 324, no. 5933, p. 1394-5, Available from <https://www.ncbi.nlm.nih.gov/pubmed/19520944>. ISSN 0036-8075 (print), 1095-9203.

Sources

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