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Clinical Study

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Clinical study was defined as a prospective study comparing the effect and value of interventions against a control in human beings. In summary, any clinical treatment is conducted to study the trial subject may obtain any expected effect or the effect is quantitatively significant compared with the non-treated patients.

The clinical studies divided three phases such as the phase I, the phase II and the phase III. Prior to the phase I, animal test (*in vivo* test) and *in vitro* test (test tube test) were conducted as non-clinical study. The effectiveness and safety of the test drug were studied.

In the phase I clinical trial, the safety of the test drug to the human being was mainly studied. The trial subject is the healthy male volunteers. To confirm the safety level of the test drug, it must be confirmed the danger level of the test drug. By carrying out the dose finding study, from how much amount the risk was occurred (maximum safety level). As a whole, 20-80 trial subjects are tested. For the injection of a certain dose to the tested person, subjective symptoms, objective symptoms, blood pressure, pulse rate, body temperature and so on were recorded. In addition, blood was sampled for blood examination. To estimate safety level, absorption, distribution, metabolism and excretion (pharmacokinetics) were studied.

In the phase II, it divides two phases. They are early Phase II and late phase II. The main purpose is to determine the appropriate dose and the way to use. As a whole of the phase II, 100-200 volunteers were necessary. The early phase II, safety and effective level and pharmacokinetics were studied to the patients. In the early phase II, test drug is evaluated if it conducts study further or not. In this phase, number of volunteer was around 50.

The late phase II, pharmacokinetics and adaptation were clarified. How much amount causes the expected evaluation items and endpoint (clinically optimum amount and the range) and dose-setting (dose-response) was evaluated and determine the dose in the phase III clinical trial.

In the phase III clinical trial, the final test prior to the market release, dose range and the way to use, validity, safety, characteristics were evaluated through comparison test and general clinical study. Comparison test indicates between patients group treated with test drug and patients group treated with control to confirm if there may be any significant validity and safety. As a control in Japan, the approved drug is used and in USA, the placebo was used. General clinical study, in case test drug was used in phase III, the validity and safety was compared to the wider rage of age, sickness and seriousness of the patients than the phase II. More than 100 patients were tested.

Through phases I to IIII, validity and safety were confirmed and approved permission to release the test drug to the market.

After approval, when the approved test drug taking together with other drug, long-period use, applied to the severe degree patients and any side effect may observe. For the purpose to observe if this kind of symptoms may occur or not, post-market surveillance was conducted.

It is practically impossible to conduct the clinical study to all patients before test drug is approved, therefore statistical sampling is conducted. The result of the clinical study must be generalizability and external validity is equal to the clinical study. To attain generalizability and external validity, random sampling as sampling procedure is most desirable but it is impossible, therefore model patients are utilized as a sampling.

The sample patients were divided two groups with test drug-application group (treated group) and control-application group (control group). Two groups must be homogeneous in terms of comparability and internal validity only exception of kind of application drug. This is essential to confirm validity and safety of the test drug.

This is the brief story of the approval to the official agency. Strict studies are required, but still remains several problems. For example, *in vivo* test (animal test) does not always correspond to the *in vitro* test (test tube test). And *in vivo* test (animal test) does not always correspond to the clinical study. Clinical study has also problems. The trial subject of the phase I should not be only male and must include female because male and female differs sensitivity to the drug. The phase III data change depending on the matter the doctor knows which test drug is and which is placebo. The last problem can be partially settled down using double or triple blind test, which is quite troublesome. Even double and triple blind test are not always completely satisfactory. Post-marketing surveillance can be found serious side effects and so on. These means current approval procedures of the test drug in clinical study are not always satisfactory. Further tests may be required. But if required so tough, drug companies escape from drug manufacturing because food preparation and PR is much easier and income is more than that of drug manufacturing. Food PR must be prohibited as the efficiency PR of the food is quite resemble to the drug and food is easier prepared and unnecessary clinical study. Food approval must be more tight resemble to drug approval. This case can be seriously said in Japan. In Japan many food and antibacterial agent PR is conducted. This is because they are not required clinical study. Tough clinical study is only required to drug manufacturing.

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