Design and Principles of Early Phase Clinical Trial

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The interdisciplinary positionings of clinical pharmacology and of modern drug research have become an essential item for all principles of development which today are and in future will beimposed upon us in a world undergoing changes more and more rapidly, as well as within an accelerated development in almost all fields of the scientific, economic and social life. The course of development of a new drugs is very complicated and needs the subtle planning of all departments, participating in an interdisciplinary efforts or needs planning in cooperation with institutions which must be contacted, as comprehensive experts, for clarifying special problems. Clinical pharmacology is interpolated into the developmental network plan of a new substance at a very early stage in order to prepare the necessary measures for phase I examinations in man. When preclinical works of development show clearly that a substance disposes of a certain range of action, and when the first evaluation makes siginficant a promising therapeutic applicability in cases of certain indications, the tasks of the clinical pharmacologist commence. The first application of new substances, i.e., of potentially therapeutically efficacious ones, must be regarded as very problematical. However, under conditions of correspondingly subtle planning, it is possible to evaluate without great risk in phase I results concering dosage, tolerance, pharmacokinetics, and pharmacodynamics of a new substance. The course of phase I requires a determination of a strategy of medical investigation as well as of corresponding experimental plans based on a carefully thought out conception, the reason for both items being the necessity to eliminate as thoroughly as possible scientific and economic failures. In phase I, especially the following factors must have been thought out very carefully : Sequence of tolerance studies, of clinicopharmacological and pharmacokinetic metabolic studies, and of the first tolerance test. Details will be discussed.