Assessment of Adverse Effects in Early Phase Clinical Trials : General Aspects

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Tolerance studies in volunteers help to bridge the gap between animal and patient studies and reduce exposure to ineffective therapy during the early evaluation of a new drug in man. The nature, severity and incidence of adverse reactions of new drug will be detected and assessed based on preclinical toxicology and pharmacolgical knowledge.

The physician with responsibilitly for the study must have adequate extensive experience of cardiovascular and CNS techniques in new drug investigations and an intimate knowledge of resuscitation equipment.

All volunteers should have full clinical examination, hematology, clinical chemistry, chest x-ray and tests for hepatitis before being considered for investigation.

The clinical monitors using the instruments including checklist and questionnaire should be employed in order to detect all expected and unexpected adverse reactions. The causality of an adverse event should be definitely determined.

The tolerance studies would be studied sequentially as following : single-dose study, multiple-dose study and multiple-dose placebo-controlled study. With placebo-controlled study, the statements about causality and prevalence can be more definite but more subjects are required.