Assessment of Adverse Effects in Early Phase Clinical Trials : Central Nervous System

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In the early phase of clinical trial of a new drug, adverse CNS effect should be investigated and assessed whether the drug has psychotropic effect or not. Adverse CNS effects can be measured as a change in the aspects of behavior, vigilance/attention & cognition, neurophysiological activity of the brain, and neuroendocrinological functions from the subject's baseline(pre-treatment) condition.

The assessment and measurement of adverse CNS effects can be made with specific and objective technique which can be classified into 4 groups :

1) Psychometric tests assess many aspects of information processing, sensorimotor coordination, short-term or working memory, reaction time, psychomotor functions arithmetic and logical reasoning.

2) Neurophysiological & psychophysiological measurements such as quantitative pharmaco-EEG(Q-EEG), brain electrical activity mapping(BEAM) allow objective assessment of CNS effects induced by drugs.

3) Behavioral assessments using comprehensive check lists of behavioral and mood effects, i.e. as Minnesota Multiphasic Personality Inventory(MMPI).

4) Neuroendocrinological measurements of secretion of anterior pituitary hormone and other hormones, such as GH, ACTH, LH, FSH, and TSH.