Beth Israel Deaconess Medical Center

Novel Software-based Method for Assessment of Drug Toxicity and Efficacy Using a Non-invasive Systems Biology Approach (BIDMC 895)

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Background:
A fundamental problem in the development of novel therapeutic agents and monitoring of approved drugs is the assessment of their safety and efficacy. Current screening assays for efficacy and toxicity of pharmacologic and non-pharmacologic interventions are based primarily on local effects and the measurement of a limited range of markers. Such measures generally fail to account for systemic effects associated with integrative feedback ("systems biology"). Thus, a drug might appear to have beneficial effects in the short-term, or based on site-specific actions where a more sustained use might be associated with lethal toxicities not detectable by conventional assays.

Invention:
The present technology is a software-based method to quantify the complexity of physiological signals such as heartbeat intervals readily obtained from an EKG. The method is based on the discovery that pathologic and other maladaptive states are characterized by a loss of complex information, such as less complex variation between heartbeat intervals. Drugs and other therapeutic interventions that enhance system complexity have been shown by this method to be associated with positive therapeutic effects, whereas interventions that degrade system complexity have been shown to be associated with adverse effects that may escape detection by conventional assessments.

Commercial opportunity:
- Assessment of therapeutic efficacy and toxicity in preclinical and clinical studies
- Screening tool for new drug candidates
- Assessment of approved therapeutic drugs and other non-pharmacologic interventions for potential toxicities.

Patent status: US patents issued: 7,601,124 and 7,882,167

Related publications: Available upon request

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