Study examines effects of Ibudilast and metamphetamines

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John W. Tsuang, M.D., principal investigator at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed), in conjunction with Steven J. Shoptaw, Ph.D., from the UCLA Department of Family Medicine, is spearheading a Phase I clinical safety trial that for the first time examines the effects of Ibudilast when administered with metamphetamine (MA), an addictive stimulant that is closely related to amphetamine. Ibudilast is a non-selective phosphodiesterase inhibitor known as a modulator of glial activation in the central nervous system; the role of these glial cells is to regulate the repair of neurons after an injury, such as the neurocognitive deficits caused by long-term MA addiction. The study is being funded by the National Institutes of Health National Institute on Drug Abuse (NIDA).

More commonly known as "speed," "meth" or "ice," MA is long lasting and toxic to dopamine nerve terminals in the central nervous system (NIDA). According to the Substance Abuse and Mental Health Services Administration (SAMHSA), a 2009 survey revealed that 1.2 million Americans ages 12 and older had abused MA at least once prior to the year they were surveyed. According to the SAMHSA, MA dependence causes devastating personal and public health consequences, particularly in the Western and Midwestern United States.

"Currently, there are no approved medications to help treat MA dependence," said Dr. Tsuang. "Through this study, we are working to determine the effects of Ibudilast - combined with relevant doses of MA - on heart rate and blood pressure, and whether or not Ibudilast alters the

way in which the body absorbs, distributes, and metabolizes MA. The development of one or more medications to reduce MA abuse, when implemented with evidence-based behavioral and counseling interventions, would have obvious public health significance."

Dr. Tsuang and his colleagues are utilizing a randomized double-blind, placebo-controlled within-subject crossover design to determine the safety and tolerability and subjective and reinforcing effects of MA in 12 participants who are not seeking treatment for MA dependence. The participants will be treated with oral Ibudilast (20mg BID and 50mg BID) and placebo.

Recent research suggests that glial cells may be important in modulating the rewarding properties of drugs that are abused, including MA. Research also suggests that MA-induced glial activation may help reduce the damage done to the central nervous system and associated cognitive dysfunction via glial cell secretion of pro-inflammatory cytokines, which are proteins that interact with cells of the immune system in order to regulate the body's response to disease and infection.

Dr. Tsuang is hoping that following the initial safety trial, physicians will be able to utilize Ibudilast in treating patients with MA dependence to help them improve memory and reduce the damage done to their central nervous system due to MA abuse.

Provided by Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed)

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