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UCSD Clinical Trial to Assess Effects of Drug Regimens on HIV-Related Neuro-Cognitive Impairment

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Debra Kain

A clinical trial is being conducted by researchers at UCSD's HIV Neurobehavioral Research Center (HNRC) to discern which antiretroviral treatments are most effective in treating HIV-related disease in the brain and central nervous system. The study includes the use of novel functional magnetic resonance (fMRI) techniques to non-invasively image the brain changes underlying cognitive impairment due to HIV.

UCSD researchers are seeking 120 patients with documented HIV infection and associated neuro-cognitive impairment for this multi-site study.

"The prevalence of HIV-associated brain disorders is continuing to increase due, in part, to the prolonged life span of individuals who are surviving well on highly active antiretroviral treatments (HAART)," said Ronald Ellis, M.D., Ph.D., associate professor in neurosciences at UCSD and principal investigator of the randomized study. "This study is designed to provide a definitive answer to a question that has occupied the attention of hundreds of researchers and clinicians for many years: do antiretroviral medications that directly target the brain actually provide better outcomes for patients in terms of cognitive benefit?"

While clinicians report central nervous system-related deficits that are more subtle than the dementia evident before the advent of HAART drugs for patients with HIV, the milder symptoms continue to substantially reduce an individual's quality of life and everyday functioning.

"The development of more effective drugs or therapeutic strategies for treating HIV-related central nervous system or cognitive impairment is critical," Ellis said, adding that prolonged effects on the brain of patients living with HIV could increase dramatically over the years, even in the presence of ongoing viral suppression due to HAART.

HIV often infiltrates the central nervous system soon after infection, leading to inflammation, nerve cell damage and abnormalities in the brain's white matter - all of which can affect signaling within the brain. Complications associated with HIV may include learning and memory deficits, impairment of cognitive or motor skills, or full-blown dementia.

The study's primary goal is to evaluate the effectiveness of central nervous system-targeting drugs (CNS-T), as compared to drugs without CNS-targeting treatment in patients with documented HIV infection and who show impairment in brain functioning as measured by neuropsychological tests. Participants will receive baseline evaluations to assess brain function, including a neurological examination and lumbar puncture.

The UCSD researchers say that this study will, for the first time, give researchers a more complete picture of what these drugs are doing and enable them to tailor medications to particular patients.

"Active inflammation within the brain may indicate the need for more neuro-protective medicinal therapy," said Beau Ances, M.D., an adjunct assistant professor of neurosciences at UCSD. "Some regimens are better able

to cross the blood/brain barrier than others. These higher-penetrating medications may be better suited to treat active inflammation in the brain, which can still be present even in the absence of non-CNS-related symptoms."

In a related study, Ances is using non-invasive fMRI scans to determine possible reversibility of HIV-induced brain changes that occur in some HIV patients after starting or changing regimens. He is also looking at whether these changes can be detected using fMRI with patients not yet showing any clinical signs of cognitive impairment.

"The scan might provide 'early stress test' of brain functional changes as well as serving as a way to assess the effectiveness of treatments in restoring more normal brain function," said Ances.

Interested patients who are eligible to begin or change HAART regimen, which is the current standard of care for HIV patients, and would like more information about this trial should contact Rodney von Jaeger at (619) 543-5055.

Media Contact: Debra Kain, 619-543-6163