

Study to examine new treatment for West Nile virus

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Neurological and infectious disease experts at Rush University Medical Center are testing a new drug therapy for the treatment of individuals with West Nile fever or suspected central nervous system infection due to the West Nile virus.

Rush is the only site in the Midwest enrolling patients into the \$50 million dollar, NIH-funded, Phase II clinical trial called PARADIGM.

The new drug treatment for West Nile virus that is being tested, also known as MGAWN1, is a humanized monoclonal antibody, which is a drug engineered to help the body seek and destroy the virus. During the randomized, double-blind study, patients with the signs and symptoms of West Nile virus will receive either a single infusion of MGAWN1 or a placebo.

"Currently, there are no approved treatments for people with severe West Nile virus infection and there is no standard of care that is highly effective against it," said Dr. Russell Bartt, neurologist and lead site investigator of the study at Rush. "Patients with the disease are hospitalized and receive supportive care."

"This new drug therapy has the potential of neutralizing the virus and could possibly reduce or prevent complications associated with the West Nile neuroinvasive disease," said Bartt. "This could represent a significant advancement for patients with West Nile."



The monoclonal antibody latches on to the West Nile virus in order for the body's immune system to recognize and eliminate it. The treatment will hopefully reduce the severity and also shorten the length of the disease.

The PARADIGM study will be testing the safety and tolerability of the drug therapy in infected patients. The first phase of the study of MGAWN1 tested doses in healthy adults and demonstrated adequate safety and was tolerated well.

West Nile virus is a disease transmitted through the bite of an infected mosquito. When someone is bitten by an infected mosquito, the virus can enter the <u>blood stream</u> and circulate. The virus may be eliminated, but in some cases, it may end up in the tissues in the body, lymph nodes, as well as invade neurological tissues where the virus replicates and may cause symptoms in days and weeks.

Since 1999, there have been more than 29,000 cases of confirmed West Nile virus infection in the U.S. About 20 percent of humans infected with the West Nile virus experience West Nile fever with symptoms that include fever, headache, body aches, stiff neck, muscle weakness, confusion, skin rash, and swollen lymph glands.

In about one percent of human infections, West Nile virus enters the brain and spinal cord causing severe, life-threatening neuroinvasive disease. In these types of serious cases, <u>West Nile virus</u> can cause encephalitis (inflammation of the brain), meningitis (inflammation of the coverings in the brain and spinal cord), or acute flaccid paralysis.

Provided by Rush University Medical Center

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