How an Experimental Implant May Help People With Schizophrenia

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One of the challenges of schizophrenia is that individuals living with the mental disorder often have trouble adhering to their antipsychotic medication as prescribed. But a six-month implant of risperidone as an alternative to the daily oral dose of this safe and effective treatment can help people adhere to therapy, according to recent findings released by Braeburn Pharmaceuticals and reported by Healio.

Currently, the device is called BB0817. Researchers developed the drug's delivery method based on the premise that schizophrenia can be well managed through continuous long-term treatment with antipsychotic medication.

For this latest trial, researchers at the Segal Institute for Clinical Research in Miami conducted a Phase II/Phase III study among 50 people with schizophrenia. Scientists gave half the participants 4 milligrams of oral risperidone treatment each day. The other half received three risperidone implants in their upper arm that delivered doses of the med during a six-month period.

Findings showed that from baseline to six months all participants on the implant remained stable with no meaningful clinical changes in their symptoms. Researchers also found that blood plasma concentrations of the drug remained consistent throughout the study in both groups. In addition, 94 percent of participants given the implants and offered the opportunity to re-enroll in an extension phase of the trial chose to get a second set of BB0817 embedded.

So far, the most common side effect of the medication was mild pain at the site of the implant. Additional adverse events were systemic and included restlessness, motor issues and anxiety, which appeared in less than 10 percent of participants.

"Compliance with medication is a very important clinical issue, and without it, serious consequences including relapse and hospitalization are more likely," said Rishi Kakar, MD, the study's principal investigator at the institute. "Preventing non-compliance is an important goal for any successful clinical treatment. The six-month risperidone implant, if approved, would offer physicians and patients an innovative approach to the treatment of schizophrenia."

Researchers also noted that the implant, which provides a treatment duration more than twice as long as currently marketed injectable treatments for schizophrenia, can be administered during a

short, in-office procedure.

Final results from the study's Phase III safety trial are expected later this year. After that, scientists plan to file a New Drug Application for approval of the device at the U.S. Food and Drug Administration (FDA) at the end of 2017.

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