Clinical Trial Reveals New Hope For Postpartum Depression

By Krystal Alexander — July 18, 2016

Early results from a phase II clinical trial shows promise for curbing postpartum depression (PPD), a rare but extreme mood disorder which affects new mothers. The bio-pharmaceutical company, Sage Therapeutics [1] announced the early findings of the intravenous drug SAGE-547 last week. According to a 2013 [2] publication in JAMA Psychiatry — researchers found one in seven women were diagnosed with depression.

PPD can pose a real and significant threat to the well-being of the mother and the baby, requiring immediate psychiatric hospitalization. It differs from postpartum blues or ‘baby blues,’ in that the latter is a milder form of depression, not exceeding two weeks, with no associated functional impairment.

In the double-blinded clinical trial, 21 participants were randomized in two groups: the treatment arm received SAGE-547 administered as a continuous intravenous infusion for 60 hours, while those in the control group received a placebo. Patient response was assessed using the Hamilton Depression Rating Scale (HAM-D), a well-validated questionnaire used by healthcare workers to determine the severity of depression and response to treatment.

To be eligible for the trial, patients had to meet the following criteria:

- Onset/Diagnosis of a major depressive episode between the third trimester to the first four weeks post delivery
- Less than six months postpartum
- HAM-D score of 26 or greater prior to treatment. (A score of 0-7 being considered normal.)
After 24 hours of SAGE-547 infusion, a statistically significant reduction in the HAM-D score was achieved compared to the placebo. The treatment arm showed 70 percent remission from depression, achieved at 60 hours, and maintained through to the 30-day follow up mark. What's more, there were no associated deaths or serious adverse events reported during the study.

Sage has certainly identified an area of medicine where pharmacological options have been inadequate at best. For many patients, conventional anti-depressants can take between 2-8 weeks before taking effect. With the overwhelming success seen thus far, Sage has sought to expand the Phase II clinical trial with the goal of determining optimal dosing for the use of SAGE-547 in PPD patients. Furthermore, recognizing the need for an oral therapeutic option, researchers plan to progress with a Phase II clinical trial of the oral drug, SAGE-217, in the treatment of PPD. Both drugs work by a similar mechanism of action, acting as allosteric modulators of the \textit{GABA} receptors, which play a significant role in neuronal transmission.

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