

'Wake-Up Pill' Under Study to Treat Patients with Bipolar Disorder

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A preliminary study of 85 patients with bipolar disorder shows that a drug used to treat patients with sleep disorders might also control the depressive symptoms associated with bipolar disorder. At least 44 percent of the participants in the study reported improved symptoms, a noteworthy improvement for a disorder in which new treatments are needed, according to the study's author, Mark Frye, M.D., director of the Mayo Clinic Mood Disorders Clinic and Research Program.

The study appears in the August issue of the *American Journal of Psychiatry*.

"There are very few treatments for the depressive phase of bipolar disorder and as a result there is an urgent need to evaluate potential new therapeutics," says Dr. Frye. "Mood stabilizers in general are better at treating mania than depression, but the depressive phase of the illness is far more common. We really need continued research in this area."

This study was completed in 2005 when Dr. Frye was with the University of California, Los Angeles (UCLA).

Bipolar disorder is characterized by an alternating pattern of emotional highs (mania) and lows (depression). It can range from a mild to severe condition, and there may be periods of normal behavior. (For more information about bipolar disorder, visit www.mayoclinic.com)

According to the National Institute of Mental Health, 5.7 million adults in the United States are living with bipolar disorder.

Modafinil, the drug featured in this study, is often referred to in the news media as the “wake-up pill” because it is approved by the Food and Drug Administration (FDA) to treat patients who suffer from excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work sleep disorder. During the depressive phase of bipolar disorder the symptoms include

excessive sleepiness and fatigue, so researchers wondered if modafinil could address these symptoms in patients with bipolar disorder.

“This is a placebo-controlled study with real world community impact,” Dr. Frye says. Half of the patients in the study were given modafinil, 100-200 milligrams daily, and the other half were given a placebo over a six-week period. The randomized, double-blind, placebo-controlled trial was conducted at five sites (the University of California, Los Angeles; University of Texas Southwestern; University of Cincinnati; and University of Munich and the University of Freiburg in Germany).

While the trial was small, the 44 percent response rate was greater than that of the placebo group. Forty-four percent said they felt better, while 39 percent said their symptoms were in remission after six weeks. This compares to 23 percent and 18 percent in the control group. Modafinil was not associated with any greater risk of the manic and depressive mood swings associated with bipolar disorder.

How exactly modafinil works to promote wakefulness or improve mood in bipolar disorder is not completely understood. It appears to have an entirely different mechanism of action as compared to other psychostimulants, Dr. Frye says.

Source: Mayo Clinic

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