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# Study to assess effectiveness of two OTC medications for treating alcoholism in bipolar patients

Mar 22 2017

Researchers have long wondered if medications could treat alcohol abuse. Ihsan Salloum, M.D., chief of the Division of Alcohol and Drug Abuse at the University of Miami Miller School of Medicine, hopes to answer that question in part with a new clinical trial with E. Sherwood Brown, M.D., Ph.D., at UT Southwestern Medical Center in Dallas. The study is determining if two over-the-counter (OTC) medications can diminish alcohol abuse in diagnosed bipolar patients.

The \$2.5 million, five-year trial is currently in year two and funded by the National Institute of Alcohol Abuse and Alcoholism (NIAAA) of the NIH. The study will gauge the effectiveness of citicoline and pregnenolone, over-the-counter medications used for improved brain function and mood control, as a treatment for alcohol abuse in people who also suffer from bipolar disorder. While research on the use of prescription medications for curbing alcohol abuse in people with bipolar disorder has had very limited success, smaller previous studies have shown these two OTC medications can be effective, leaving Salloum and Brown excited about their potential.

"This proof of concept study hopes to accomplish what we in the medical community have long hoped for -- a medication to reduce alcohol abuse," said Salloum. "In addition, because of their properties, the two drugs being studied could also improve patients' moods and emotional balance."

The trial targets diagnosed bipolar disorder patients because more than 60 percent of this population suffers from some sort of alcohol-use disorder. These patients are also at higher risk for suicide and co-morbidities, such as illnesses and accidents, often attributed to either their diagnosis and/or alcohol use.

Over the course of the 12-week study in Miami and Dallas, participants will be assigned citicoline, pregnenolone or a placebo and take the medication twice daily. They will also need to attend a weekly appointment at the University of

Miami Health System or UT Southwestern Medical Center for feedback.

Through 2018, the University of Miami and UT Southwestern will track patient data. If one or both of the OTC medications are successful in treating alcoholism in bipolar patients, the study will continue through years four and five. If citicoline and/or pregnenolone are deemed effective at the end of the five-year trial, larger studies will be launched to evaluate their viability in people with alcohol-use disorders who do not suffer from mental health problems.

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**Source:**

University of Miami Miller School of Medicine

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