Parents report a widely prescribed antibiotic is effective for fragile X treatment

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One of the antibiotics most commonly prescribed to treat adolescent acne can increase attention spans and communication and decrease anxiety in patients with fragile X syndrome, the most common inherited cause of mental impairment, according to a new survey study that is the first published on parents' reports of their children's responses to treatment with the medication.

Led by researchers at the UC Davis MIND Institute, the study examined parents' observations of their children's responses to minocycline — not the efficacy of treating patients with the drug. However, the researchers said that the study results are extremely promising. They led to a placebo-controlled clinical trial of treating people with fragile X with minocycline, funded by the National Fragile X Foundation.

"Minocycline Treatment in Patients with Fragile X Syndrome and Exploration of Outcome Measures" is published in the September 2010 issue of the *American Journal of Intellectual and Developmental Disabilities*. In the study, parents relate that after being treated for an average of three months, their children showed improvements in their use of language, attention levels and behavior, while experiencing mostly mild side effects.

"This preliminary survey demonstrated improvements in participants, however, a controlled clinical trial is needed to compare the efficacy of treating patients with minocycline to treatment with a placebo," said Randi Hagerman, Fragile X Endowed Chair, medical director of the UC

Davis MIND Institute and one of the world's leading experts on fragile X syndrome.

Fragile X syndrome is a genetic disorder, the result of a defect on the X chromosome. It is estimated to affect 1 in 3,600 males and 1 in 4,000 females. One-third of all children with fragile X syndrome develop autism and approximately 5 percent of children with an autism-spectrum disorder have fragile X.

The condition causes a range of disabilities, from learning disorders to mild-to-severe intellectual impairment (mental retardation) and behavioral and emotional problems. It also is associated with certain physical characteristics, including prominent ears and flexible finger joints. The symptoms typically are more severe in boys than in girls.

Minocycline is one of the most commonly prescribed medications for adolescent acne and has been in use since its introduction in the 1960s. The drug also has been found to have neuroprotective qualities and in animal models improves neurodegenerative diseases like Parkinson's and Huntington's. Interest in its use in human patients with fragile X surged after a 2009 study found that minocycline improved cognition in mice genetically engineered to have fragile X. That study's senior author was Iryna M. Ethell of UC Riverside, who also is an author with Hagerman of the current research.

Ethell and her colleagues in 2009 found that minocycline lowers the levels of matrix metalloproteinase 9 (MMP9), an enzyme present in the normal brain whose levels and activity are over-expressed in the fragile X mouse. MMP9 inhibits development of structures called dendritic spines, tiny mushroom-like projections at the ends of synapses that allow neural cells to communicate. Lowering the amount and activity of MMP9 strengthens the dendritic spines and improves the establishment and maintenance of circuits in the brain.

"It's really exciting to see applications like this of our mouse-model research," Ethell said.

For the parent study, Hagerman prescribed minocycline to patients at the Fragile X Research and Treatment Center at the MIND Institute. Other participants were treated elsewhere by their primary-care physicians. The study included a total of 53 patients, three of whom dropped out after a few days because of side effects. The remaining 50 participants, seven females and 43 males, took the drug for between two weeks and 20 months, with dosages of 25 to 200 milligrams per day. Participants ranged in age from 4 months to 25 years.

Fifty-four percent of the participants' parents said their children showed improvements in their use of language. Fifty percent said their children's attention spans improved. Forty-four percent said their children's social communication improved and 30 percent said their children's anxiety levels decreased. Most said their children experienced mild side effects, such as an upset stomach. Hagerman had wanted to learn whether the patients would experience the tooth discoloration common to individuals using tetracyclines. Reports of those side effects were minimal.

In anecdotal reports, parents said that after taking minocycline their children used more language, had clearer speech and were more understandable. Some said their children were "becoming more conversational, articulate and talkative," the study states. Parents also reported that their children were more focused and "had longer attention spans when playing, doing homework or participating in another activity."

The study findings prompted the National Fragile X Foundation to fund a two-year, $100,000 pilot study of the use of minocycline in people with fragile X. The study is examining the efficacy of using the antibiotic to treat children between the ages of 4 and 16.

"The National Fragile X Foundation is honored to be able to support a research project that has the potential to bring significant improvement, in a relatively short period of time, to individuals with fragile X syndrome," said Executive Director Robert Miller. "We know that families also are excited about this possibility. A goal of the National Fragile X Foundation is to move research forward that translates scientific breakthroughs into near-term treatments — and this study has the potential to do just that."

The study was conducted in collaboration with lead author Agustini Utari, a fellow at the UC Davis MIND Institute from the Center for Biomedical Research, Diponegoro University, Indonesia, where the prevalence of fragile X syndrome appears to be high. Utari has returned to Indonesia, where she plans to conduct a minocycline study.

"I am very excited about the opportunity to bring a study of minocycline and fragile X to Indonesia," Utari said.

Provided by University of California - Davis

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