

Name of Study: Folate Rechallenge: A Pilot Study

Locations: Baylor College of Medicine, Houston, TX; University of California, Davis, CA

Eligibility Criteria: Children/individuals of any age who have a confirmed diagnosis of autism, who are in good health and do not have celiac disease, a history of liver or renal disease, uncontrolled seizures, a known allergy to any of the study supplements, or a current acute illness. Children should be able to take medication orally, and families should be proficient in the English language.

Principal Investigator: Dr. Arthur L. Beaudet

Contact Information: Dr. Robin Kochel, 832-822-4299 or kochel@bcm.tmc.edu

Dear Parent,

I am writing this letter to offer your family an opportunity to participate in a research study being conducted at Baylor College of Medicine and Texas Children's Hospital (TCH) in Houston, TX, and at the M.I.N.D. Institute at the University of California, Davis, CA. This research project will examine the effects of high doses of folates on the behaviors of children with autism. Some families have tried folate therapy with their affected children, but the results have not been consistent. We want to understand more about positive, neutral, and worsened behavioral responses to high-dose folate supplementation and whether there is a behavioral-biochemical connection that could explain various outcomes. Knowing your child's particular response to high-dose folate supplementation may be helpful to you in making decisions about his/her diet or vitamin therapies.

If your family agrees to participate, you may be asked to bring your child either to the Clinical Care Center at TCH or the M.I.N.D. Institute (depending on your locale) on one or two occasions to confirm the autism diagnosis and/or participate in a medical exam. Your visit(s) may last between 1 and 3 hours. Trained clinicians who regularly work with children will conduct all assessments. If your family is determined to be eligible to participate, study staff will ask you to stop giving any vitamin and herbal supplements to your child for 4 weeks. After this time, you will bring your child back to TCH/M.I.N.D. for the first baseline blood draw. You will leave this appointment with a 4-week supply of one study supplement (either folic acid or placebo), with specific instructions on when and how he/she should take it. At the end of 4 weeks, your family will return to TCH/M.I.N.D. for a second blood draw. Your child will then have a 2-week period where he/she does not take any study supplements or any other vitamin or herbal supplements. At the end of the 2 weeks, your family will return to TCH/M.I.N.D. for a third blood draw. You will leave this appointment with a 4-week supply of another study supplement (either folic acid or placebo—whichever was not given during the first phase). At the end of the 4 weeks, your family will return to TCH/M.I.N.D. for a fourth blood draw. During each time that your child comes to TCH/M.I.N.D. for blood draws, we will also ask that you complete the same two forms that request information about his/her behavior. Depending on how your child responds to study supplements in this first phase of the study, he/she may be invited to continue in an extension phase. During this extension phase, he/she would be supplemented with Metafolin® for a period of 4 weeks. Metafolin® is a more active folate that the body would normally make from folic acid. The dosing and other requirements would be the same during this phase, including requests that the parents complete behavioral measures on participating children. For each visit made to TCH/M.I.N.D. as part of this study, parking costs will be validated.

If you would like more detailed information about this study and how you may participate, please contact Dr. Robin Kochel at (832) 822-4299 or email at kochel@bcm.tmc.edu. If you agree for your child to be in this study, you will be asked to sign a consent form after you have had all of your questions answered.

Thank you for your time and attention.

Sincerely,

Robin P. Kochel, Ph.D.
Assistant Professor
Department of Molecular and Human Genetics
Baylor College of Medicine