BRAIN DISCOVERIES DRIVEN BY REAL PEOPLE

The University of Minnesota Fetal Alcohol Spectrum Disorders (FASD) Program is focused on clinical care and brain research for children & adolescents with prenatal alcohol exposure.

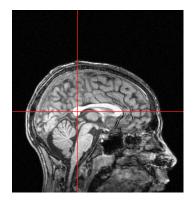
- The University of Minnesota FASD Clinic, which started in 1978, has worked with thousands of children with all levels of learning and behavior effects from prenatal alcohol exposure.
- The FASD Program works closely with the University's International Adoption Clinic, the Masonic Institute on the Developing Brain, and community agencies.
- Our research team is using magnetic resonance imaging (MRI) techniques to study the brain changes caused by prenatal alcohol exposure – changes that contribute to behavioral and learning challenges for children.
- Our research results are shared locally with families and professionals, at international FASD research conferences, and in medical and scientific journals.
- Our clinical experiences with children who have FASD guide <u>all</u> of our research questions.

THE STUDY TEAM

- Jeffrey Wozniak, Ph.D. Co-principal investigator, Professor, Director: UMN FASD Program
- Michael Georgieff, M.D. Co-principal investigator, Professor, Director: Masonic Institute on the Developing Brain
- Judith Eckerle, M.D. Pediatrician, Associate Professor, Director: UMN Adoption Medicine Program & Clinic
- Amy Gross, Ph.D., BCBA Psychologist, Associate Professor, Interim Director, UMN FASD Clinic
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Fetal Alcohol Spectrum Disorders (FASD) CLINICAL TRIAL



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Driven to Discover™

ALCOHOL AND THE DEVELOPING BRAIN

Children who were exposed to alcohol during pregnancy are at risk for developmental delays.

- No level of alcohol consumption during pregnancy is safe for the child.
- Brain damage can occur even with limited alcohol exposure.
- Alcohol can cause brain damage at any time during pregnancy.
- Developmental delays range from minor to severe (across a "spectrum").
- Rates of attention problems and learning disorders are high in children exposed to alcohol during pregnancy.

University of Minnesota researchers are testing an intervention in young children who have neurodevelopmental effects of prenatal alcohol exposure:

- The research is focused on testing the intervention during a timeframe when the child's brain is still rapidly developing.
- We are testing nutritional supplements like <u>choline</u> (the investigational drug being tested in this study) to determine if they can improve brain development and cognitive functioning.



CHOLINE

This research, supported by grants from the *National Institutes of Health*, is studying the effects of choline for brain development in Fetal Alcohol Spectrum Disorders (FASD). Choline, a nutrient contained in many foods, is being studied in this research as an investigational drug under the oversight of the Food and Drug Administration. In order to best determine how to administer choline for this purpose, children will randomly receive choline for either 3 or 6 months.

The goal of the clinical trial is to find out if different lengths of choline supplementation improve memory and learning in children for whom these areas of functioning are known to be delayed.

- We have developed a fruit-flavored drink mix containing choline that the child takes for the purposes of this study.
- The study will use age-specific measures of brain development, some of which have been developed by the University's Center for Neurobehavioral Development and the Institute of Child Development. These include detailed measures of intelligence, learning, memory, mental flexibility, and behavior.
- The study, which has enrolled 120 children since 2010, is entering its fourth phase and will be enrolling 60 additional children. The study will continue until 2026.



YOU CAN HELP

If you have a child under the age of 6 years who was exposed to alcohol during pregnancy, we would like to speak with you about participating in this study.

Each child's development will be followed for nine months. Two visits to the University will be scheduled at your convenience.

There will be no cost to you. We will provide a full supply of the fruit-flavored drink mix to be given to your child at home daily. All expenses, including testing, developmental assessments, mileage and convenient parking, will be paid for by the study.

Contact us:

fasd@umn.edu

