Maternal probiotic supplementation for improved neurodevelopmental outcomes in infants of diabetic mothers (IDMs)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- pregnant women in their second or third trimester with a diagnosis of gestational diabetes - screening for gestational diabetes involves a 2-step (screening test followed by a diagnostic test) with screening done between 24 and 28 weeks of gestation in a non-fasting state. If the screening threshold is met or exceeded, patients receive a oral glucose tolerance test (OGTT) - BMI 18.5-45 kg/m2 at first prenatal visit - age 21-45 at time of delivery ● Pregnant women who report during enrollment procedures that they have social support for and intention to exclusively breastfeed for at least 3 months (breastfeeding intentions are known to be correlated with actual behavior) ● Singleton pregnancy

Exclusion Criteria:

- alcohol consumption >1 drink per week during pregnancy/lactation - tobacco consumption during pregnancy or lactation - inability to speak and understand English - known congenital metabolic, endocrine disease (other than GDM), or congenital illness affecting infant feeding - history of type I Diabetes - mothers currently taking over the counter probiotic preparation

Conditions & Interventions

Conditions:
Women's Health
Keywords:
women's health, pregnancy, pregnant women, gestational diabetes

More Information

Description: This is pilot study designed to test the hypothesis that maternal probiotic supplementation is associated with infant gut microbiome variation and improved neurodevelopmental outcomes as measured by ERP performance. The primary aim is to determine if maternal probiotic supplementation during pregnancy and lactation is associated with improved recognition memory performance in infants of diabetic mothers (IDMs). This will involve recruitment and enrollment of pregnant mothers who have been diagnosed with gestational diabetes and randomization to an intervention or control group. Women in the intervention group will receive a standardized probiotic supplement during the third trimester of pregnancy through the first month of lactation. We will compare the IDMs who are exposed to probiotics via maternal supplementation or not with respect to auditory and visual ERPs at 1 and 6 months of age to determine if probiotic supplementation is associated with improved hippocampus function in infancy. The secondary aim is to examine whether maternal probiotic supplementation during pregnancy and lactation is associated with differences in maternal milk and infant fecal microbiome signatures as well as maternal milk and infant serum inflammatory protein levels. Microbial analysis will be performed on infant stool and maternal breast milk samples at one and six months of age. Infant serum and maternal breast milk inflammatory protein levels will be measured at one and six months postpartum.
Contact(s): Lydia Golden - golde406@umn.edu
Principal Investigator: Marie Hickey
Phase: NA
IRB
Number: STUDY00016313
System ID: 38904