



What if we could improve children's respiratory health by changing the bacteria that live in their airways?

MOTHER SEED STUDY INFORMATION BOOKLET

The Center for Asthma Research at Vanderbilt University Medical Center (VUMC) is recruiting participants for the “MOdification Of THE Early-Life Respiratory Microbiome Through Vaginal SEEDing” (MOTHER SEED) study.

Study Purpose and Background

What is the main purpose of this study?

The main purpose of this study is to evaluate if vaginal seeding of a child's nose is a feasible and safe procedure.



What is vaginal seeding?

Vaginal seeding involves swabbing a baby's body part (such as the nose) with the mother's vaginal fluids (that is, secretions from the mother's vaginal area) soon after birth by cesarean section (C-section).

Babies born vaginally are covered with their mother's vaginal fluids. These fluids are present at birth in the child's nose, mouth, and skin. Some studies have suggested that these fluids could be a source of “good” bacteria, which may help in the development of a child's immune response (that is, how a child's body defends itself against infection or reacts against different exposures). In contrast, babies born by C-section are not exposed to the bacteria present in the mother's vaginal fluids. This could explain why children born by C-section seem to be at a higher risk of developing common respiratory diseases later in life (such as bronchiolitis, hay fever, or asthma).

The idea behind vaginal seeding of a child's nose is that this procedure could transfer some "good" bacteria from a mother to her baby after birth by C-section, thus trying to imitate what happens when a child is naturally exposed to the mother's vaginal fluids during a vaginal delivery.

Who Should Participate?

Pregnant women scheduled for a C-section at VUMC may be eligible to participate in this study.

What Should You Expect?

If you are eligible for this study, your child may be randomly assigned to receive an intervention called vaginal seeding. This intervention involves swabbing your baby's nose with your vaginal fluids soon after birth. This is done to expose cesarean-born babies to the same bacteria they would have been exposed to at birth if they were born by vaginal delivery.

You will not be able to choose or know the group to which your baby is assigned for the duration of the study.

There will be several study visits while you are pregnant, around the time your child is born, and throughout your child's first 6 months of life.

Each study visit will include specific study activities, which mainly consist of collecting information and samples from you and your child.

You can find a timeline of the study visits and activities at the end of this document.

What Type of Information Will We Collect from You and Your Child?

For this study, information will be collected by asking you questions, reviewing your and your child's health records, and performing limited physical exams on you and your baby.

Some of the information we will collect through these methods include personal data (such as names, dates of birth, home addresses, phone numbers, and email addresses), sociodemographic characteristics (such as household income, level of education, and type of insurance), environmental and lifestyle exposures (such as plans for

breastfeeding, daycare attendance, and use of tobacco products, drugs, or alcohol), past and current medical history (including a history of sexually transmitted infections), family history, medication use and immunization history, and information on the course of your pregnancy, child's birth characteristics, child's development, and any health issues you or your child may have.

You can find out what we learn from the information we collect at the end of this document.

What Type of Samples Will We Obtain from You and Your Child?

The type of samples that we will collect from you include blood, urine, and vaginal samples. The type of samples that we will collect from your child include nasal, stool, and urine samples.

You can find out what we learn from the samples we collect at the end of this document.

How Long Will You Be in the Study?

We will follow you and your child throughout pregnancy and until your child is 6 months old.

Where Will the Study Take Place?

Study visits will be mainly conducted in person around scheduled prenatal care visits or well-child visits at VUMC locations.

Why Should You Participate?

Your participation will help us learn about potential interventions to change the bacteria living in the nose of children born by C-section.

Study Compensation

You will be compensated up to \$450 for your participation.

Study Funding

Funding for this study is provided by the National Institutes of Health (NIH).

For More Information

For more information about this study, please contact or visit us at:

Phone: (615) 875-5772

E-mail: motherseed@vumc.org

Mailing address: Monroe Carell Jr. Children's Hospital at Vanderbilt
2200 Children's Way, Doctor's Office Tower Suite 11215
Nashville, TN 37232-9500

Website: <https://www.vumc.org/motherseed>


Thank you!


Families like yours make this research possible.




motherseed

MODIFICATION OF THE EARLY-LIFE RESPIRATORY
MICROBIOME THROUGH VAGINAL SEEDING

 (615) 936-5552

 motherseed@vumc.org

 Monroe Carell Jr. Children's Hospital at Vanderbilt
2200 Children's Way, Doctor's Office Tower Suite 11215
Nashville, TN 37232-9500

 <https://www.vumc.org/motherseed>