Background about the Study
This study is hoping to find ways to prevent the development of asthma in children. Previous studies suggest that introducing certain supplements into an infant’s diet can affect their immune system (the part of our body that helps fight infections) and prevent the onset of asthma. You have been asked to think about participating in this study as part of the control group.

During pregnancy and infancy, it is suspected that factors both inside and outside of our bodies can have an affect on the development of our immune system. One way of thinking is that a certain combination of these factors can lead to an imbalance in the immune system and the development of asthma. One theory is that this imbalance in the immune system is caused by reduced exposure to bacteria and viruses. If this is true, then exposure to a certain bacteria may help establish a healthy balance in the immune system.

Most of the participants in this study are infants with one parent with asthma, and are therefore at increased risk for developing asthma themselves. Some will be fed a probiotic supplement called *Lactobacillus GG*, to see if it reduces their chances of developing asthma compared to the other infants, who are not being fed a probiotic supplement.

Your child is being asked to participate as part of the control group for this study, because he or she is not at increased risk for developing asthma. He or she will not be asked to take a probiotic supplement, or any other kind of medication, for study purposes.

Our study will only involve healthy infants. We will not include infants with severe, chronic illness or those infants with intravenous (IV) lines.

Goals of the Study
The primary goals of this study are to see if the active *Lactobacillus GG* supplement taken during infancy can prevent or delay the appearance of the early signs of asthma. Some of the early signs include: frequent wheezing, wheezing without a cold or the flu, frequent “runny” nose, and eczema. There are also immune system signs that are sometimes associated with asthma. These can be determined using blood tests.

Some studies have shown that the presence of certain bacteria in the stool is associated with allergic diseases, such as asthma and eczema. One of the goals of this study is to compare the types of bacteria in the stool of infants at increased risk for asthma with those of infants who are not at increased risk (such as your child).

Carrying out the Study
Most of the infants involved in this study are healthy, full-term, newborns with normal birth weights whose mother or father has a history of asthma. This is because parents with asthma are more likely to have children with asthma. We will study about 280 newborn infants at increased risk for asthma; half of the infants will receive the active *Lactobacillus* supplement and half will receive an inactive ingredient that does nothing (a placebo).

We will also study about 20 newborn infants who, like your child, do not have a family history of allergic disease. These infants will form our control group. They will not be fed either a probiotic or placebo supplement.
Participation in the study for the control group infants begins within 96 hours following birth. A member of the research team will complete a questionnaire with the infant’s mother about: the types of food she did, or did not eat during the last part of her pregnancy, information about her household, and information about her children’s and the baby’s father’s allergy history. If the baby qualifies for the study, after obtaining the consent of the parent, a member of the research team will access the infant’s medical record to make sure that there are no reasons why the infant should not be part of the study. Some of the reasons include: having difficulty feeding, being ill or having an IV. The research team member will also collect a stool sample from the infant’s diaper, if possible, while the infant is in the Newborn Nursery.

During the main part of the study, the parents of control group infants will be given kits to collect a sample of stool from their infant’s diaper, when their infant is 1, 3, 6 and 12 months old. When the infant is 12 months old, the parents will be asked to come to UCSF Children’s Hospital’s Pediatric Clinical Research Center for a parent interview and a blood draw from the infant. The purpose of the blood draw is to look for immune system signs of allergic disease.

Control group infants will be followed until they are three years old. During the first year of life, they will be followed by monthly telephone interviews with their parents. During the next two years, after all stool samples have been collected, they will be followed by telephone interviews every six months. Parents are also free to contact study investigators by telephone if they have any questions.

At the end of the study, the types of bacteria in the infants’ stool will be compared with those of the other two groups of infants in the study: those at increased risk for asthma who were fed the probiotic supplement, and those at increased risk for asthma who were not fed the probiotic supplement. We can then analyze the information to see if the types of bacteria found are different if the infants are at increased risk for asthma, and if the infants are fed the probiotic supplement.

Participation in this study is completely voluntary. Making a decision not to participate will not affect your care or your infant’s care in any way.

Dr. Cabana and other members of the research team are available to answer any questions that you may have regarding participation in this study. Please call toll free: 1-866-913-8477 (TIPS)

Contact Information

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