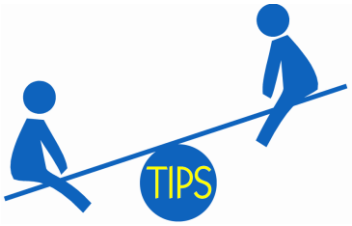

Study Summary

Trial of Infant Probiotic Supplementation to Prevent Asthma (TIPS)

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.

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. This way of thinking also suggests that little or no exposure to bacteria and viruses during infancy leads to this imbalance in the immune system.

If it is true that this imbalance in the immune system is caused by reduced exposure to bacteria and viruses, then exposure to a certain bacteria may help establish a healthy balance in the immune system. Probiotics are bacteria that are normally found in the human intestine and have been used to provide certain health benefits, such as the prevention of diarrhea.

The probiotic used in this study is *Lactobacillus GG*. This bacterium is normally found in yogurt and other food products. It is the most studied probiotic available with more than 100 studies conducted. *Lactobacillus GG* is already used by many people as a supplement.

Studies also suggest that early exposure to *Lactobacillus GG* is associated with a decreased risk of developing eczema, a long-lasting, extremely itchy skin rash. Eczema is very frequently found in people who have asthma.

Our study will only involve healthy infants. We will not include infants with severe, chronic illness or those infants with intravenous (IV) lines. In this way, we are using *Lactobacillus* in the safest possible manner.

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.

Carrying out the Study

All 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; half of the infants will receive the active *Lactobacillus* supplement and half will receive an inactive ingredient that does nothing (a placebo).

Participation in the study for the mother begins in the last part of pregnancy. A member of the research team will complete a questionnaire with her about: the types of food she does, or does not eat during the last part of her pregnancy, information about her household, whether she has children who have asthma (if appropriate), and information about her asthma or the baby's father's asthma.

Participation in the study for the child begins within the first day or two following birth. After obtaining the consent of the parent, a member of the research team will examine the infant 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. This examination is usually done in the Newborn Nursery.

Being assigned to the active supplement or the inactive ingredient is done by a random process (like flipping a coin). Because we do not wish to influence the results, neither the parents nor the research team will know whether the infant is receiving the active supplement or inactive ingredient. This information will not be made known until after all the data collection has been completed.

Both the active supplement and inactive ingredient are packaged in capsules and look the same. Once per day the parent or caregiver pulls the capsule apart and pours the contents of the capsule into a small cup. A small amount of breast-milk, formula or water is added and the mixture is put into a dispensing syringe. This is the kind of syringe used by parents to give medicine to an infant. The mixture is then given to the infant. This is done for six months.

Throughout the study, members of the research team keep in regular contact with the parents by telephone. Parents are also free to contact the research team to answer any questions. In addition, there are a total of 6 follow-up visits at the UCSF Hospital or an outpatient center beginning at 1 month until the age of three years. These visits involve a physical examination and parent interview.

A special committee of research and medical professionals (called the Data Safety Monitoring Board) looks at the information collected by the study to see if there are any problems experienced by the study subjects. The purpose of this group is to protect the well-being of the study subjects.

After all the study information has been collected, the type of supplement (active or inactive) received by each infant will be made known to the research team. We can then analyze the information to see if the active supplement prevented or delayed the appearance of the early signs of asthma.

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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