

Who Can Take Part In The Study?

Infants and toddlers between the ages of 2 months and 12 months, who were born at full term (37 weeks) and with a birth weight of 2.5 kg.

What Does The Study Involve?

- At the first visit, the doctor will explain the study and answer all of your questions. Should you choose to have your child participate in this study, you will be asked to sign a consent form. The study will require your child to be vaccinated and the child must remain in the office for observation for 30 minutes after the vaccination.
 - For children that are 12 months of age at this visit; a small amount of blood (no more than a teaspoon) will be drawn.
 - Younger children will have their blood drawn when they are older, either at 5 or 7 months of age.
- At subsequent visits, depending on the age of your child and the study group they are a part of; a blood sample and vaccination will occur in the same manner as described above.

- In between visits, you will receive a diary to complete and will receive a telephone call from your doctor's staff to follow-up on your child's health since their last vaccination.

For further information please contact:

Insert site contact information

Site Name:: Pediatric Associates, PSC

Address: 2865 Chancellor Dr.

Crestview Hills, KY

Contact Person:: Marian Crossman, RN

Telephone:: 341-5400 X3034

Meningococcal Vaccine Study



About The Study

Your doctor is participating in a clinical research study to evaluate an investigational meningococcal vaccine for infants and toddlers, an age group in which there is no vaccine currently available. You and your child are invited to participate.

Depending on the age of our child, you will be attending 2-7 office visits, with telephone calls between visits. Most of these office visits happen at the same time as the usual "well baby" visits.

You will need to keep the scheduled appointments, answer questions about your child's health and follow the directions of the study staff. Your child will still receive all vaccinations according to the standard pediatric immunization series, so their normal care will not be interrupted in any way.

What is Meningococcal Disease?

Meningococcal disease is a serious illness caused by bacteria. These bacteria may cause meningitis (infection of the brain and spinal cord coverings), septicemia (infection of the bloodstream) or both.

Although disease is rare, onset and progression of the disease can be very rapid. About 10% of infected people die from the disease. In non-fatal cases, those affected experience long-term disabilities, such as brain damage, loss of a limb, or deafness. Preventing the disease through the use of a meningococcal vaccine is important.

There are two vaccines approved for use in the United States for meningococcal disease; however, there are no meningococcal vaccines licensed in the United States for the age group 2 years and under.



How Important is a Multi-Strain Meningococcal Vaccine?

Five types of meningococcal bacteria (A, B, C, Y, and W135) are responsible for the majority of cases of meningococcal disease worldwide.

What is the TetraMen-T (A, C, Y, W-135) Vaccine Study?

TetraMen-T is a new investigational vaccine that has been developed with the potential to protect against types A, C, Y and W-135 meningococcal infection.

The aim of this study is to evaluate the safety and immune response of the TetraMen-T vaccine in infants and toddlers.

What are the Potential Benefits?

In addition to the satisfaction of helping with the development of a new vaccine, all infant subjects will receive the licensed vaccines Pentacel®, Prevnar®, hepatitis B vaccine and rotavirus. Once they reach the age of 12 months, these infants as well as all toddlers, will receive the licensed vaccines Prevnar®, M-M-R₁₁® and Varivax.