

What is a vaccine clinical study?

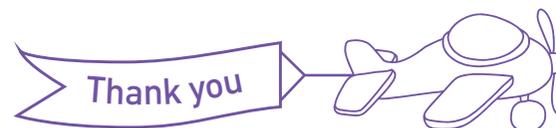
In a clinical study of an investigational vaccine, participants are enrolled to help researchers answer questions about the study vaccine, find out if it works or works better than other vaccines, and find out if it has side effects.

What is an investigational vaccine?

An investigational vaccine is a substance that is being tested in clinical studies. It has been reviewed by an ethics committee for testing in people and may or may not be approved by the government health agency for use in the general population at a later time.

Why should I take part in this study?

Clinical studies (also called clinical trials) are important for medical advances. Current vaccines are only available because of clinical study volunteers.



Thank you for your interest in this study to learn more about a study vaccine for pneumococcal disease.

[Study site contact information]

Pneumococcal Vaccine Study



Your baby will soon be exploring the world.

That's why we're exploring a new vaccine.

Now enrolling: A study of an investigational pneumococcal vaccine in healthy infants

Study number: AFX3772-003

○ Ask your child's doctor about this vaccine study. ○

Why is this study important?

Streptococcus pneumoniae is bacteria that affects adults and children across the world. It can lead to pneumococcal disease and cause serious illnesses such as pneumonia and meningitis. It is also the most common cause of ear infections and sinus infections.

There is currently an approved vaccine to prevent pneumococcal disease called PCV13, however this vaccine does not prevent all types of pneumococcal infections. Therefore, there is a need for additional research of pneumococcal vaccines.

Pharmaceutical companies use clinical studies like this one to learn more about investigational drugs or vaccines before they are made available to the public. This study will compare an investigational vaccine to the approved PCV13 vaccine. Study volunteers can help us in this important research. Thank you for considering participation in this study.

What is the purpose of this study?

Researchers are evaluating the safety and tolerability of the investigational vaccine called AFX3772, when compared to the approved vaccine PCV13. They also want to find out more about how the body's immune system reacts to AFX3772. The immune system helps the body fight against infections.

Who can participate in this study?

To be eligible for this study, your child must:

- Be a healthy, full-term infant (at least 37 weeks gestation)
- Be between 42 and 90 days old
- Have never received a pneumococcal vaccine
- Have a parent or legal guardian who is able to give informed consent

This is not a complete list of study requirements. The study doctor will review all the requirements with you.

How long will this study last?

This study will last approximately 17 months.

What can I expect if I allow my child to participate?

After screening and enrollment, participants will be assigned to one of two study groups. In one group, participants will receive the investigational vaccine, AFX3772, at four separate study visits. In the second group, participants will receive the approved vaccine, PCV13, at four separate study visits. You and the study doctor will not know which group your child is in. (In case of an emergency, the study doctor can find out which group your child is in).

You and your child will need to come to the study center up to eight times during this period. Some visits may be performed at your home or by telephone, with approval from the study doctors. There will also be at least four telephone calls that will take place 8 days after the first dose of the vaccine is given.

Lab tests, physical exams, and other assessments and questionnaires will be conducted as part of the study.

What are my costs for my child to take part in this study?

You do not have to pay for the study vaccine, study supplies, or tests that are part of the clinical study. You do not need to have insurance to participate. Your child will not be compensated for participating in this study, but you may be reimbursed for parking and transportation expenses that are incurred as part of your child's participation in the study.

What risks are involved if I allow my child to participate?

There are possible risks involved with any clinical study. Your study doctor will review the potential risks with you, and your child will be closely monitored throughout the study.

