Your doctor has given you this brochure because a child of yours has myopia (also known as nearsightedness) and may be eligible to participate in a clinical research study. The information in this brochure will answer some of the questions you may have about the study and clinical research. Please talk to your doctor to learn more.

What is a clinical research study?

A clinical research study is conducted to learn whether a new drug, treatment, or method is safe and effective for people who have certain ailments or illnesses. Clinical research studies, also known as clinical trials, follow strict scientific standards to ensure they produce the best data available for health care decision making.

What's the purpose of this study?

The study is testing an investigational eyedrop in children who have myopia. The study doctors want to learn if it may help slow the progression of nearsightedness in children.

This pediatric myopia study is enrolling now.

Talk to your doctor or contact us today to see if your child may qualify.

CHILDHOOD IS A CRITICAL TIME FOR EYESIGHT DEVELOPMENT!

Optimizing vision in childhood is key to lifelong eye health and a bright future.

CONNECTICUT EYE CONSULTANTS, P.C.

Does my child qualify to join the study?

He or she may qualify to participate in this study if:

- They are 3 to 14 years of age (male or female)
- You (patient/guardian) are able to administer eyedrops
- They are in good general health
- They have myopia (nearsightedness) in both eyes

Why should I participate in this study?

There are a variety of reasons why people participate in clinical research studies. Some study volunteers want to help advance science, and your child's participation in this study could help doctors learn more about the treatment of myopia in children.

Some research study volunteers are interested in gaining access to new drugs or potential treatments. If your child participates in this study, they will receive either the investigational eyedrop or placebo at no cost. All study-related medical care will also be at no cost. Finally, they may receive at no cost eyeglasses (or daily-wear contacts) to be worn as required.

What happens during the study?

To join our study, you must read and sign an informed consent document to show that you understand the study and what's required. A study doctor will explain the study's procedures, its possible benefits and risks, and answer any questions you have before you sign.

After you give consent, the study doctor and staff will give your child some tests to make sure that he or she is eligible to participate. If so, your child will participate for up to 48 months. During this time, your child will receive 1 drop in each eye every night at bedtime. Initially, this eyedrop may be the investigational eyedrop or an eyedrop that contains no medication. At month 36, children may remain on the same drop or they may be switched to the investigational eyedrop or to an eyedrop that contains no medication, but all will receive the investigational drop at some point in the study.

If your child's nearsightedness significantly progresses between months 18 and 36 (compared to their first visit), and if this change is confirmed 6 months later, they will be treated with the stronger dose until month 48.

You and your child will also have regular visits at the study clinic. The staff will work with you to find convenient times for your visits. Your child can leave the study at any time, for any reason.

What about my private health information?

The study doctor and staff will handle your child's personal health information in a confidential manner. Personal health information includes both your child's study data and original medical records. To ensure your privacy, your child's name and other identifying information will not be attached to any records or samples released for research purposes. Instead, the records and samples will be identified only by a code.