How often will my child be examined?

The study will last for up to 4 years. Your child will have an examination at one day, one week, one month and then every three months following surgery. In addition, your child will have his or her vision tested by a traveling examiner when 12 months old. An examination-under-anesthesia will also be performed just before the vision test to check the eye for the correct glasses or contact lens prescription or any problems. Your child's eye doctor may decide that more examinations are needed for your child's care, unrelated to the study. Each examination will include a brief check of your child's vision and the health of the eye that had cataract surgery.

Sometimes you will be asked to fill out some forms about how your child is doing and the effect that having a child with a vision problem has had on your family life. The forms take about 30 minutes to complete.

Periodically someone will also contact you by telephone to ask how much of the time your child has been wearing glasses or a contact lens and the eye patch. We will also ask you to fill out a one-week "Eye Care Diary." This information will be collected just for the purpose of this study and will not be shared with your child's eye doctor.

What costs will be the parent/guardian's responsibility?

The costs of the office examinations and surgery will be your or your insurance company's responsibility. The study will provide you with eye patches, glasses, and contact lenses. In addition, you will be paid $100 quarterly to cover travel expenses.

What happens if we move or if our insurance changes?

If you move, we will help you find a qualified pediatric ophthalmologist in your new area to assume your child's care. If your insurance coverage changes, we likewise will attempt to find an ophthalmologist who can continue to provide expert care for your child under your new plan.

Why should I volunteer to have my child participate in IATS?

The best reason to volunteer for IATS is to be a part of a clinical study designed to provide answers about how to best treat unilateral cataracts during infancy. The results may not directly benefit your child.

What will be our responsibility if we agree to take part in the study?

If you agree to have your child be a part of the study, you will be expected to try your best to have your child wear the contact lens or glasses prescribed. It will also be expected that you will patch your child's good eye half of their waking hours. You will be agreeing to bring your child to all study visits following cataract surgery.

A study like IATS takes a lot of effort from everyone involved. You and your child will be a very important part of the research team and you have a commitment to the study.

What do I need to do to have my child participate in IATS?

You will be advised if your child is eligible for the study. If you want your child to be in the study, you will be asked to sign a form giving your consent. You will also be asked to provide information for the study's coordinating center in Atlanta, Georgia.

IATS

INFANT APHAKIA TREATMENT STUDY

An Evaluation of Treatments for Cataracts in Babies

Information for Parents

What is a cataract?

The eye's lens is like a camera lens and has to be clear. A cloudy lens prevents light rays from being focused on the retina, the light sensitive tissue at the back of the eye. The degree of visual impairment caused by a cataract varies and depends on how much of the lens is blocked by the cataract.

How are cataracts treated?

Small cataracts may not require treatment if they do not significantly affect the vision in the eye. Larger cataracts, which severely interfere with vision, require immediate surgery. Using microscopic surgical techniques, an ophthalmologist removes the lens. All cataract operations involve an opening into the eye and on children are performed under general anesthesia. Lasers cannot remove cataracts.

How is vision corrected after cataract surgery?

Once the cloudy lens is removed, the child will need a substitute lens to focus images on the back of the eye. This can be done with a contact lens or a lens implant. The lens implant, also known as an intraocular lens, can either be put in at the same time the cataract is removed or in another operation when the child is older. Glasses alone are not usually satisfactory to focus an eye after cataract surgery if the other eye is normal because of the large difference in the strength of the two eyeglass lenses.

Contact lenses

Different types of contact lenses are available for an infant following cataract surgery. One type is made out of silicone and can be worn on an extended wear basis. The contact lens must be removed frequently to be cleaned. Another type is rigid and needs to be removed each night to be cleaned. Since an infant's eye grows rapidly, the prescription of the lens will need to be changed periodically.

Intraocular lenses

Intraocular lenses are used to focus an eye following cataract surgery. The plastic lens is placed inside the eye in the same location as the original lens. The optical correction is constant and the images seen by both eyes are of equal size. The long-term safety of intraocular lenses in babies has not been established. Since the intraocular lenses cannot be easily removed, a lens with a power less than what is initially needed is implanted in anticipation of the eyes growing and eventually the eyes becoming focused with the lower power. As a result, the baby is given glasses to provide additional focus until the eye has grown further.

Amblyopia

A cataract in an infant can cause poor vision resulting from amblyopia or what is commonly referred to as a "lazy" eye. While the visual system is developing, the brain must receive clear images from both eyes. If this does not happen, the part of the brain that controls vision will not develop properly. For this reason, when a cataract develops during infancy, surgery should be performed as soon as vision is threatened.

Cataract surgery is only the first step in treatment. Glasses or contact lenses are also necessary and the good eye must be patched until the vision improves in the weaker, operated eye. Patching the good eye forces the baby to use the weaker eye. If patching is not done after cataract surgery, good vision usually fails to develop. Even after the weak eye has become stronger, patching or other treatment must be continued on a part-time basis until the child is visually mature which is usually when the child is about 7 years of age.

What is the Infant Aphakia Treatment Study?

The Infant Aphakia Treatment Study is being conducted to find out whether it is better to treat a baby with a cataract in one eye with a contact lens or an intraocular lens following cataract surgery. Approximately 100 infants will take part in the study at 13 pediatric eye care centers in the United States.

The study is coordinated by the Emory University School of Public Health and the Emory University Department of Ophthalmology in Atlanta, Georgia. It is funded by the National Institutes of Health.

Which treatment will my child receive?

Your child will be randomly (like the flip of a coin) assigned to receive either an intraocular lens during cataract surgery or to wear a contact lens following cataract surgery. If your child is assigned to wear a contact lens, the cataract will be removed but no intraocular lens will be placed in the eye. Your child will be fitted for a contact lens soon after cataract surgery and will then wear the contact lens on a full-time basis. If your child is assigned to have an intraocular lens implanted, the intraocular lens will be implanted during the same surgery that the cataract is removed. After surgery, your child will be prescribed glasses to be worn during all of your child's waking hours. In both treatment groups, you will be asked to patch your child's normal eye one half of the hours he or she is awake each day.