Amblyopia Treatment Study

Augmenting Atropine Treatment for Amblyopia

Information for Parents

National Eye Institute
NATIONAL INSTITUTES OF HEALTH

What is amblyopia?
Amblyopia is sometimes called "lazy eye." It is the medical term used when the vision in one of the eyes is reduced because the eye is not being used properly. The eye itself looks normal, but it is not being used normally because the brain is favoring the other eye.

How common is amblyopia?
Amblyopia is one of the most common causes of decreased vision in children. The condition affects approximately 2 or 3 out of every 100 children.

What causes amblyopia?
Amblyopia may be caused by any condition that affects the normal use of the eyes and visual development. This can be due to an imbalance in the positioning of the eyes (*strabismus),* which can be either a turning in (*esotropia)* or out (*exotropia*) of the eyes. Sometimes amblyopia is caused by a difference in the glasses prescription of the two eyes (such as one eye having more nearsightedness, farsightedness, or astigmatism than the other eye).

How is amblyopia usually treated?
Treatment of amblyopia generally involves making your child use the 'weak' eye. This is most often done either by having your child wear a patch over the "good" eye or by putting an eye drop in the good eye to blur the vision. If the treatment helps but some amblyopia is still present, we don't know whether increasing the treatment will help further. When atropine is used, increasing treatment involves blurring the good eye even more by removing the correction from the lens in the glasses. The replacement lens is a blank lens that does not help the vision. It is referred to as a "plano" lens. This study is being done to see if removing the correction from the glasses for the good eye will improve the weak eye more than just continuing the atropine drops for a longer time.

What is the Pediatric Eye Disease Investigator Group?
The study is being conducted by the Pediatric Eye Disease Investigator Group (PEDIG). Your child's eye doctor is a member of this group. The study will include about 158 children at pediatric eye centers across North America. The Jaeb Center for Health Research is the coordinating center (data center) which is organizing the study. The National Eye Institute is providing the funding for the study.

What are the study procedures?
There are two phases in this study. In the first phase, you will put an atropine drop in your child's good eye each Saturday and Sunday. There will be follow-up visits every 6 weeks until there is no improvement in the vision of the weak eye.

In the second phase, half of the children will continue putting an atropine drop in the good eye each Saturday and Sunday. The other half of the children will put an atropine drop in the good eye each Saturday and Sunday plus have the correction removed from the glasses for the good eye.

Your child will have a follow-up visit 10 weeks later. At this visit, we will instruct you to stop the atropine and return two weeks later to check your child's eyes after the atropine has worn off. If the amblyopia is still present and the vision in the weak eye has improved at the first 10-week visit, then your child will have additional follow-up visits every 10 weeks until there is no more improvement. Otherwise, your child will have completed the study. Your child's vision and eye alignment will be checked at each additional 10-week visit.

What will be your responsibilities if you agree to have your child participate 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 use the treatment that is prescribed. During the weeks when your child is using the atropine drop, you must also be willing to record on a calendar each day that the atropine drop was used. You must also be willing to be contacted by phone shortly after enrollment and then about 5 weeks after starting the second phase. A study like this takes a lot of effort from everyone involved. You and your child will be a very important part of the research team, and like its other members, you will have a commitment to the study.

What costs will be your responsibility?

The following will be provided by the study at no charge to you: (1) Study visits, (2) Atropine eye drops, (3) Non-prescription sunglasses or clip-on sunglasses if needed, (4) New glasses, if your child is assigned to the atropine and plano lens treatment, (5) Reading glasses if needed for schoolwork, (6) New lenses for your child's glasses if the vision in the good eye worsens and the glasses prescription changes.

To cover travel and other visit related expenses, you will be paid $30 for completing each exam, including the randomization visit, and the follow-up visits during both phases, up to a maximum of $300. The number of visits will vary for each person in the study, but we expect an average of 6-7 visits.

Why should I volunteer to have my child participate in the study?

You and your child will be part of a research study designed to provide answers about how to best treat amblyopia. Although the results may not be of direct benefit to your child, they are expected to benefit other children with amblyopia.

What do I need to do to have my child participate in the study?

You will be told 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 (Informed Consent Form) giving your consent. This form will give more details about the study.

Coordinating Center:

Jaeb Center for Health Research
Tampa, FL
Phone: 888-79PEDIG
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If you would like further information or are interested in participating in this study please contact:

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Directions to Optometry Services

From the North:

Take State Route 315 S to King/Kinnear exit.
Turn left onto Kinnear Rd (Kinnear turns into Olentangy)
Take Olentangy River Road to King Ave. (3rd light).
Turn left onto King Ave.
Take King Ave. to Cannon Drive.
Turn left onto Cannon Drive.
Take Cannon Drive to Medical Center Drive.
Turn right onto Medical Center Drive.

From the South:

Take State Route 315 N to Medical Center Dr. exit.
Continue to go straight onto Medical Center Drive.

Parking-Hospital Garage:

Follow Medical Center Drive to Westpark St. Turn Left onto Westpark St.
The Hospitals Parking Garage is located on your left.