

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. In many cases amblyopia is caused by a difference in the glasses needed to correct the eyes (such as one eye having more nearsightedness, farsightedness, or astigmatism than the other eye).

How is amblyopia usually treated?

Treatment of amblyopia usually starts with optical correction (glasses). After treatment with glasses alone, if the vision is not normal, doctors often try other treatments like having the child wear a patch over the “good” eye or putting an eye drop in the good eye to blur the vision.

Why are we doing this study?

The purpose of this study is to find out if treating amblyopia with glasses and patching at the same time improves vision as well as treating amblyopia first with glasses and then with

patching, if needed.

What is the Pediatric Eye Disease Investigator Group (PEDIG)?

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 272 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?

If you decide to have your child take part in the study, a computer program will be used to decide whether your child will start the study wearing glasses first (and wear an eye patch for 2 hours each day later if needed) or whether you will start the study wearing glasses and an eye patch 2 hours each day at the same time. This is like flipping a coin to decide which approach will be followed. If your child wears an eye patch, he/she will also wear a sensor on inside of the eye patch that will record the amount of time that the patch is worn.

To know if your child is eligible for this study, your child will have his/her vision tested in a temporary pair of glasses that will hold lenses that your eye doctor has determined to provide best vision. If your child’s vision in these glasses has improved too much, the study will end, and your child will not participate any further. If his/her vision in these glasses is still reduced to the level required by the study, then he/she will continue in the study and will be prescribed

glasses, which will be ordered through an optical shop and paid for by the study

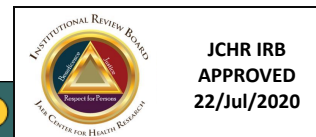
After the glasses are made, your child will come back to his/her eye doctors’ office for a visit where he/she will wear their glasses for the first time. He/she will not wear the glasses until they come back for the visit. After wearing the new glasses for at least 10 minutes, your child’s vision will be checked. If your child’s vision is too good for the study while wearing the new glasses, the study will end, but your child will be able to keep the new glasses. If your child’s vision is still bad enough for the study while wearing the new glasses, your child will then be able to participate fully in the study. Your child’s eye alignment, depth perception, and contrast sensitivity will be checked. He/she will answer questions about his/her eyes and how they feel. As the parent or legal authorized representative (LAR), you will also answer questions about your child’s eyes.

Your child will return every 8 weeks for the next 56 weeks, repeating the same tests of vision. At each follow up visit, your eye doctor will let you know if your child’s treatment needs to be adjusted following the study, depending on how your child’s vision responds to the prescribed study treatment.

If you provide your mobile number, you will receive a text message before each visit to remind you of your appointment.

What will be my responsibilities if I agree to have my child participate in the study?

If you agree to have your child be a part of the study, you will be responsible for bringing your child to





all follow-up visits and to try your best to have your child use the treatment that is prescribed. During the study, you must also be willing to record on a calendar the amount of time your child uses the treatment prescribed each day. 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 my responsibility?

The study will pay for visits that are done just for the research study. You and your insurance company will not be responsible for the cost of visits done just for the research study. The study will not pay for usual care visits. Usual care visits are those that would occur even if your child is not in the study. The cost of usual care visits will be your or your insurance company's responsibility like it would be normally. The study glasses and patches will be provided to you at no cost.

To cover travel and other visit-related expenses, you will be paid \$40 for completing each follow-up exam, up to a maximum of \$400.

Why should I volunteer to have my child take part 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.

tmp3B7.tmp6-22-18



What do I need to do to have my child take part 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 provide you with more details about the study.

Coordinating Center:

Jaeb Center for Health Research
Tampa, FL
Phone: 888-797-3344
Email: pedig@jaeb.org



Amblyopia Treatment Study

A Randomized Trial to Evaluate Sequential vs Simultaneous Spectacles plus Patching for Amblyopia in Children 3 to <13 Years Old

Information for Parents

