

Amblyopia Treatment Study
*A Randomized Trial of Full-time Bangerter Filters versus Part-time
Daily Patching for the Treatment for Amblyopia in Children*

Parent Information Sheet

What is amblyopia?

Your child has a condition known as amblyopia. Amblyopia, which is sometimes called “lazy eye,” is the medical term used when vision is decreased because one of the eyes is not being used properly. Amblyopia is one of the most common causes of decreased vision in children. Sometimes amblyopia is caused by crossing in or turning out of the eyes. Other times this is caused by a difference in the glasses prescription between the two eyes (such as nearsightedness or farsightedness). Treatment of amblyopia generally involves making your child use the “weak” eye. This is most often done either by having the child wear a patch over the “good” eye or by putting an eye drop in the good eye to blur the vision. Amblyopia can also be treated by putting a piece of plastic on the glasses lens of the good eye. The piece of plastic is called a “Bangerter filter.” Some children prefer the filter because they can still see through it. Some children think it looks better than a patch.

What are the study procedures?

The purpose of the study is to find out whether the Bangerter filter works as well as two hours of daily patching. In this study, half of the children will get a Bangerter filter placed on the lens of their glasses over their good eye. The other half of the children will wear a patch over the good eye for 2 hours a day. While wearing the patch or the glasses with a Bangerter filter, your child will need to do close-up activities (those involving eye-hand coordination) for at least 1 hour a day.

About 170 children who have reduced vision in one eye will take part in the study at pediatric eye care centers throughout North America. Your child will have 4 follow-up visits at 6 weeks, 12 weeks, 18 weeks and 24 weeks after treatment is started. At each visit, your child’s vision will be checked. The eye doctor will also check to make sure his/her eyes are straight. At the 6-week visit and the 24-week visit, we will ask you and your child to complete a questionnaire. The questionnaire has questions to see how you feel about the patching or Bangerter filter treatment your child is receiving. At the 12-week visit, your doctor will perform a dilated refraction to see if your child’s glasses need to be changed. If the study requires that your child’s glasses be changed, the study will pay for the new lenses or glasses. At the either the 12 week or 18 week visits, if the amblyopia is not improving, some children may be prescribed an increase to six or more hours of patching a day or a change in the Bangerter filter to one that blurs the vision in their good eye even more.

What will be your responsibilities if you agree for your child to take part in the study?

If you agree to have your child be in the study, you will be expected to supervise your child wearing the patch 2 hours a day or glasses with a Bangerter filter and make sure your child comes to all office visits. You will need to make sure your child does the close-up activities at least one hour every day while wearing the patch or the glasses with a Bangerter filter. 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 have a commitment to the study. The 4 required follow-up visits will be paid for by the study. If more visits are needed for your child’s care, they will be your or your insurance company’s responsibility. You will be provided the treatment materials needed for the study at no charge. These include eye patches or Bangerter filters. Your child must be in the correct distance glasses before entering the study. Glasses required before the study will not be provided by the study. If the study requires a change in your child’s glasses during the study, new glasses will be provided at no charge by the study. If your child’s doctor recommends new glasses during the study but the study does not require the change (optional change), you will be responsible to pay for these glasses. To cover travel and other visit related expenses, you will be paid \$25 for each follow-up visit up to a maximum of \$100.

What do you need to do to have your 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 giving your consent. This form, called the Informed Consent Form, will give more details about the study.



Dr. Marjean Taylor Kulp
The Ohio State University College of Optometry
338 West 10th Avenue
Columbus, Ohio 43210
614-688-3336 or kulp.6@osu.edu

