



JCHR IRB
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INFORMATIONAL VIDEO

Scan the following QR Code with your smart phone device to view a video with information regarding the study:

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<https://vimeo.com/901570078/b5d9e6a345>

What is intermittent exotropia?

Intermittent exotropia (IXT) is the medical term used to describe a condition where one or both of your eyes sometimes turn out.

How common is intermittent exotropia?

IXT is the most common form of exotropia in children. Exotropia is when the eye drifts out. It affects about 32 out of 100,000 children under 19 years of age every year. Its cause is unknown.

How is IXT treated?

IXT can be treated with surgical or nonsurgical treatments. Long-term surgical treatment outcomes are disappointing, with high failure rates due to recurrence or under correction. Patching is a commonly used nonsurgical treatment for which there is some evidence of short-term treatment benefit when prescribed 2-3 hours/day. The purpose of this study is to see if full-time patching can improve

distance control of IXT after 3 months of treatment.

What are the study procedures?

Your child will need to have an enrollment exam to check whether they are eligible for the study. You and your child will each be asked to complete a brief survey about IXT symptoms and how IXT affects you and your child. The eye doctor will measure how often and how far your child's eye drifts out, how well your child can turn their eyes in, and whether both eyes are seeing when the eye drifts out. The vision in each eye and depth perception will also be checked.

If your child is eligible for the study, a computer program will be used to decide which treatment your child gets.

Your child will be treated one of two ways:

- Patching full-time (all waking hours of the day) for 3 months.
- No patching (observation only) for 3 months.

In both treatment groups, the glasses will have regular correction, if your child needs it. Your child must wear the glasses all waking hours every day for 3 months.

You should not agree to have your child be in the study unless you are willing to have your child receive patching full-time. You will not be able to choose which treatment your child gets.

Three months after starting the study, your child will return to their study eye doctor to repeat the testing that was done at enrollment. You and your child will also

again. You will be asked how often your child has worn their patch, if necessary.

How many children will participate?

We expect about 82 children will take part at about 30 pediatric eye care centers across the U.S.

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 expected to speak with study staff on a phone call between visits and to bring your child in for the follow-up visit. You will be expected to try your best to make sure that your child wears their patch, if necessary.

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 National Eye Institute will provide funds for services specific to the research study, but will not cover patient services considered to be routine care. The study will pay for visits that are done just for the research study. Any additional visits that are part of routine care would be your or your insurance company's responsibility.

If your child receives the patching treatment, the study will provide patches at no cost to you.

To cover travel and other visit-related expenses, you will be given \$100 for completion of the enrollment/randomization visit, and \$100 for the 3-month follow-up visit.



You will receive payment for completed visits even if your child leaves the study before the end. If you have travel expenses that make it difficult for you to return for study visits, additional funds may be available as described in the Informed Consent Form.

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 IXT. Although the results may not be of direct benefit to your child, other children with IXT are likely to benefit from the results of the study.

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.

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.

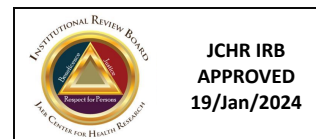
The Jaeb Center for Health Research is the coordinating center (data center) that is organizing the study. The National Eye Institute is providing the funding for the study.

IXT7 Parent Info Brochure



Site Contact Information:

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Intermittent Exotropia Treatment Study 7

A Randomized Trial of Full-Time Occlusion Therapy for Intermittent Exotropia in Children

Information for Parents

