A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia

Informed Consent Form

December 18, 2019

NCT02807350

ADDENDUM TO THE CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia

STUDY DOCTOR'S INFORMATION

Name:
Contact Number:
Site Name:
Site Address:
Emergency (24-hour) Number:
Study Coordinator Name/Contact:

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A "minor" is a person under the age of 18. A legally authorized representative (LAR) for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian. In this form when it says "your child" it means the minor under your care.

NEW INFORMATION

Your child was enrolled in the above-named research study. Your child is currently participating in the study or else has finished participating in it. This form is called an "addendum to the consent form." The purpose of this form is to give you more information about the study and to ask to follow your child for a longer time.

It is important that you understand the information in this form. You may ask questions at any time.

Since the time you signed the original consent form for this study, new information related to the study has become available. As we mentioned in the original consent form, one potential risk of overminus glasses is that they could cause nearsightedness to worsen, but we were not sure if this was true. Nearsightedness is when a person has trouble seeing things clearly far away, but no problem seeing things up close. After collecting data on more than 300 children, we have noted a faster increase in nearsightedness in children treated with overminus glasses than with regular glasses or no-correction glasses. This faster increase in nearsightedness with overminus glasses happened more often in children who were already nearsighted when they started the study. Because of this new information, we are stopping treatment with overminus glasses.

WHAT DOES THIS MEAN FOR MY CHILD?

For children who are still in the treatment part of the study (these children have not completed their 12-month and 15-month study visits yet.)

Whether or not your child is wearing overminus glasses, if your child is in the treatment part of the study, we are asking your child to return early for their next visit (12-month or 15-month visit). At this time, we will give your child a new pair of glasses which will be paid for by the study. The new glasses will have your child's regular correction or no-correction; there will not be any overminus correction. If

your child has trouble seeing things far away in their current glasses, the new glasses should make things clear. Your child may have needed new glasses anyways, no matter which type of glasses they were wearing. At this time we will also tell you whether he/she started out wearing the overminus glasses or regular glasses.

For children who haven't completed their 18-month visit yet

We are adding some testing at the 18-month visit. Your child would need to get eye drops so the eye doctor can see if your child needs new glasses. The eye doctor may also use a machine to take some measurements of your child's eyes.

For all children who were enrolled in the study

We are asking you to allow your child to be in the study longer than we originally planned. You had previously agreed for your child to be in the study for 18 months. Now we are asking you and your child to stay in the study for 18 more months. If you agree to take part, your child will have one or two more visits. One visit will be 24 months (2 years) after the original study started. Depending on when your child was enrolled, your child may have this visit or it might be too late. The other visit will be 36 months (3 years) after the original study started. Everyone will have the 36-month visit. Collecting data at these extra visits will help us find out more about the effects of the overminus glasses.

If you agree to these extra visits, your child's vision will be tested. The eye doctor will also see how well your child can hold their eyes straight. At both visits your child will need to get eye drops so the eye doctor can see if your child needs new glasses. The eye doctor may also use a machine to take some measurements of your child's eyes. We do not know if your child will be helped by having the extra follow-up visits. We may learn something that will help other children.

You do not have to allow your child to continue to take part in the study. It is up to you. You don't have to say okay to the 1-2 extra visits. You can decide to have your child finish the original study but not do the extra visits. You can even say okay now and change your mind later. All you have to do is tell us. You and your child will not be treated differently if you decide to stop being in the study.

ARE THERE ANY COSTS?

If your child is still participating in the original study:

Your child will receive study paid glasses (lenses and frames) at each 12-month, 15-month and 18-month visit that is completed (up to 3 pairs of glasses depending on how many study visits your child has left).

You will be given $50 by debit card, check, or gift card for your time and travel for each 12-month, 15-month and 18-month visit that your child completes (up to a maximum of $150 depending on how many study visits your child has left).

If your child participates in the 24-month and/or 36-month visits:

Your child will receive one pair of study paid glasses (lenses and frames) for completing the first of these two visits (24-month or 36-month).

You will be given $50 by debit card, check, or gift card for your time and travel for each follow-up visit that your child completes (24-month and/or 36-month visits, up to a maximum of $100 if both visits are needed).

PREVIOUS INFORMATION

Everything else in the consent form that you last signed is still valid. This includes the potential benefits, risks, and the use and disclosure of your child's health information.

If you would like the information in the original consent form to be reviewed with you, please let your study team know. They will review the form with you if you would like. You can also ask for another copy if you cannot find your original copy.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study, this addendum, a research illness or injury; or have concerns, suggestions, or questions about the study, then contact the study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

Have questions about your or your child's rights as a research participant
Wish to talk about your concerns or suggestions about the research
Want more information about the research, or
Want to provide comments about the research.

Minor's Full Name (printed)**:** _____

Minor's Legally Authorized Representatives (LARs) Permission

I, _____ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

☐ Natural or Adoptive Parent; ☐ Legal Custodian; or ☐ Legal Guardian

By signing below, you agree to allow your child to continue to take part in this study. Your signature means that:

you have read this informed consent form addendum
you have been given the chance to discuss the study changes and extra visits and to ask questions to your satisfaction
you freely choose to allow the participant to continue in the study, you/the participant can withdraw at any time, and you will receive a copy of this consent form.

Please check one box below to let us know whether you agree to allow your child to continue participating in the original study (the first 18 months).

My child has already completed or is no longer in the original study (the first 18-months).

OR

YES -- I agree to allow my child to stay in the study through 18 months

Please check one box below to let us know whether you agree to the extra follow up visits.

YES -- I agree to the extra follow up visits at 24 months (if needed) and 36 months.

OR

NO – I do not agree to the extra follow up visits at 24 months (if needed) and 36 months.

_____ _____
LAR Signature Date

Person Obtaining Consent

I certify that to the best of my knowledge the participant or LAR(s) understand(s) the nature, demands, risks, and benefits involved in the participation of this study.

_____

Investigator/Designee's Printed Name

_____ _____

Investigator/Designee's Signature **Date**