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

Informed Consent Form

July 22, 2020

NCT04378790

CONSENT TO TAKE PART IN A RESEARCH STUDY

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

STUDY DOCTOR'S INFORMATION

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

SUMMARY

In this form, when it says "you" it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). Please see the next section called "Legally Authorized Representatives (LAR)" for more information about who can be a LAR. This would be like a parent reviewing the information for their child to be in the study. In this case, "you" would mean "your child."

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

The study is being done to find out if treating amblyopia (worse than normal vision in one eye) with glasses and by wearing a patch at the same time is better than treating amblyopia first with glasses and then with a patch if needed later on.

- **You will be asked to be in the study for about 56 weeks. The study will involve either wearing glasses and a patch at the same time or first wearing glasses before starting to wear a patch (if needed). You will see your eye doctor about every 8 weeks for 56 weeks. At each visit, you will have your eyes examined and your vision tested.**

- **Wearing glasses and using patching are done as part of regular care to treat amblyopia. This means that the risks for the study are not expected to be greater than the risks that you would have if you were not in the study. The most likely risks are some skin discomfort from the patch.**

- **The possible benefits are that your vision might improve more or might improve faster, but that is what the study is trying to find out.**

- **If you do not participate, you may still seek care to treat your amblyopia like you normally would.**

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A "minor" is a person under the age of 18. A LAR for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian.

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have worse than normal vision in one eye. This condition is called amblyopia. The goal of this study is to learn things that may help people with amblyopia see better.

Your study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently as a person just because you didn't want to be in this study. Also, your regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by the Pediatric Eye Disease Investigator Group. It is being paid for by the National Eye Institute. The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the glasses or patches in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

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. Up to 544 children with amblyopia at about 95 doctor's offices in the US and about 5 sites outside the US and will be in the study. The study will last for 56 weeks (just over 1 year).

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must:

- Be 3 to < 13 years old
- Have amblyopia
- Have normal vision in your good eye

Also, you must not:

- Have worn glasses or contact lenses

- Have been treated for amblyopia
- Have scheduled or plan to schedule strabismus (eye alignment) surgery in the next 56 weeks
- Plan to wear contact lenses in the next 56 weeks

Your study doctor and staff will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?

You will have your vision tested in a temporary pair of glasses that will hold lenses that your eye doctor has determined to provide the best vision. If your vision in these glasses does not meet the study guidelines, the study will end for you, and you cannot participate. If your vision in these glasses still meets the study guidelines, then you can continue in the study and you will be prescribed glasses which will be ordered at an optical shop.

You will need to come back for a visit where you will wear your glasses for the first time. You should not wear your glasses until you come back for the visit. After wearing your new glasses for at least 10 minutes, your vision and alignment of your eyes will be checked. You will also answer some questions about your eyes and how you feel. If you do not meet the study guidelines while wearing your new glasses, the study will end for you. However, you will be able to keep your new glasses. If you still meet the study guidelines while wearing your new glasses, you will then be able to participate fully in the study.

If you decide to take part in this study, a computer program will be used to select whether you will start the study only wearing glasses and wear a patch later if needed or whether you will start the study by wearing glasses and a patch at the same time. This is like flipping a coin to decide which group you will be in. Both groups will need to wear glasses all day, every day when awake. The patching done at the start of the study or later in the study will be for two hours per day, seven days per week.

You will need to come back to the eye doctor every eight weeks during the study for 56 weeks (just over a year). At each visit, you will have your vision and alignment tested and will answer questions about your eyes and how you feel. If you provide your contact information, you will receive a text message before each visit to remind you of your appointment.

At each visit, your eye doctor will determine if your vision has stopped improving or if your amblyopia has gone away. If you are in the group that starts with only glasses and your amblyopia improves, you will continue to wear your glasses. If your vision stops improving, you will then start patching for two hours per day, seven days per week. You will continue to wear your glasses and patch until your vision stops improving or your amblyopia goes away. If your vision has stopped improving with glasses and patching, your eye doctor will re-check your eyes with dilation drops to make sure that the prescription in your glasses is still correct, even if your amblyopia goes away. If your vision stops improving but you still have amblyopia, your doctor may give you additional treatment for your amblyopia. If your amblyopia goes away, you will stop patching and only wear your glasses.

The table below shows what will happen at each visit.

Visit	Consent	Vision testing in trial frames	Demographics / Medical History	Check eyeglasses prescription	Vision testing	Ability to focus	Eye alignment	Visual ability	Quality of Life questionnaire	Asking about using the glasses and patching
Enrollment Visit	X	X	X							
Baseline / Randomization Visit				X	X	X	X	X	X	
8-Week Visit				X	X	X	X	X	X	X
16-Week Visit				X	X	X	X	X	X	X
24-Week Visit				X	X	X	X	X	X	X
32-Week Visit				X	X	X	X	X	X	X
40-Week Visit				X	X	X	X	X	X	X
48-Week Visit				X	X	X	X	X	X	X
56-Week Visit				X	X	X	X	X	X	X

If you are in the group that wears both the glasses and patch at the same time, you will wear your glasses and patch until your vision stops improving or your amblyopia goes away. If your vision stops improving but you still have amblyopia, your doctor may give you additional treatment for your amblyopia. If your amblyopia goes away, you will stop patching and continue to wear your glasses.

For both groups, if your amblyopia has gone away but then comes back during the study, you will start patching again for two hours per day, seven days per week.

Both groups will have their patch time monitored. This will be done by placing a small temperature sensor under the eye patch. The sensor is small and could be harmful if eaten. The sensor will record temperatures which will be used to estimate how much time the patch is worn. You will be given instructions on how to place the sensor. You will also be asked to record how much time you wear your glasses and patch on a calendar.

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study. There is a small risk of irritation or an allergic reaction to the patch. If this happens, a different type of patch will be given to you. There is a very small chance with patching that the vision in the patched eye may be reduced. This reduction in patched eye visual acuity almost always goes away when the patching is stopped. There is also a very small change that patching could cause the eye to turn out of alignment, or cause you to see double, but this is very rare. The temperature sensor worn under the patch (if needed) is small and could be harmful if eaten. Data collected from other studies so far have shown that the sensors did not get into the eye because it is stuck to the patch and is pressed to the skin, but this is possible.

Unknown Risks

It is always possible that anyone patching for the first time may have an allergic skin reaction. Also, there may be additional risks from the patching or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Risks to Confidentiality

This study will be capturing some information about you that includes identifiable personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

You will be receiving secure text messages in this study to remind you of your appointments. The text messages are called secure, because there are steps in place to help keep people from seeing these messages that are not supposed to. It is possible that someone else may see the text messages on your phone. If they do, they might know that you are in a study or see a detail about the study. You will receive text messages before each of the visits.

Study Questionnaires/Surveys

This study will involve asking you some questions about your eyes. If any questions make you uncomfortable, you can refuse to answer. You can decide to take a break or stop taking part in the study at any time. You will be asked about whether you are worried about your eyes or whether they affect you and your family. The risk of these questions are that you may feel uncomfortable answering them. Your response to these questions will not be shared with your parents unless your doctor is concerned about your safety or wellbeing.

Please discuss the risks with your study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits are that your amblyopia may get better but that is what the study is trying to find out. People who take part in this research study will add to new knowledge that may help other people with amblyopia.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include standard treatment like patching, eye drops (atropine), other research studies, or you may choose not to do anything. Your study doctor will discuss these choices with you.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not be treated differently as a person. Also, your regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

You can decide to stop getting text messages at any time. You will need to tell your study doctor if you would like to stop receiving text messages. You can still be in the study if you do not want to get text messages anymore.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- If you do not follow the study instructions
- The doctors think that being in the study may cause you harm
- If you experience an injury
- If you need additional or different medication

If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. The study will pay for study visits performed only for the study.

- The study will pay for the visit that you get your new glasses, as this is done just for the research study.
- The study will pay for the enrollment visit and visits at 8, 24, 40 and 56 weeks as these are done just for the research study.
- The study will not pay for visits at 16, 32 and 48 weeks as these visits are done as part of your usual care.

- If you have travel expenses that make it difficult for you to return for study visits, additional funds may be available if they are approved by the IRB.
- The study glasses and patches will be provided to you at no cost. Any additional tests and procedures will be billed to you or your insurance company like they normally would.

Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $400 for your participation. These payments will be paid as follows: $40 for each completed visit (up to ten visits). These payments will be made by gift card or check. If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

All procedures are just like regular care procedures. It is not expected that there would be any study related illness or injury. If you do have an illness or injury, then you can get care like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can.

The study does not plan to provide costs for care or other expenses relating to illnesses or injuries. Your study doctor, the study doctor's office, the Jaeb Center, and the National Eye Institute are not planning to cover payment for lost wages, direct losses, or indirect losses.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your 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 rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Your date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. Unless the law requires it, your name, address, social security number, telephone number, or any other directly identifying information will not be used to identify you.

Certificate of Confidentiality

The National Eye Institute has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Purpose of Authorization

We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign this form, including the Protected Health Information Authorization statement included in the signature box at the end of this form if you want to be in the study. When you sign this form, you give permission for the use and sharing of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this study.

Using and Sharing Your PHI

Your study doctor will collect information about you. This information includes things learned from study procedures as well as your name, address, date of birth, and information from your medical records. These are examples of identifiable information. A code number with your initials and date of birth will replace your name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Jaeb Center for Health Research

The study doctor's office will not share study results that can identify you except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your study PHI.

Who Can Receive and Use Your Study Information?
It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that are providing either funding or supplies for the study, laboratories, and centers that may receive images. In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

Can You Cancel Your Authorization?
You may cancel your permission for the collection of your study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study, except when there is a safety concern related to the study. If there is a safety concern, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

When Will the Use and Sharing of Your PHI Stop?
Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first.

The rest of your study information that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name, address, telephone number, or social security number.

Other Considerations
The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely. A copy of the information collected as part of the study will be made public

in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify you.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting. Results from the study will be sent to you in a study results newsletter after the study has been published.

Your child will receive glasses as part of the study. They will be provided at no cost to you. Your child's eye doctor may send you to LensCrafters or another contracted optician to get the new eyeglasses. In order to provide your child with new eyeglasses, the optician or LensCrafters will receive information on your child. Your child's name, birth date, and study identification number will be given to the optician who is making the eyeglasses. If your child is to receive study-paid eyeglasses through LensCrafters, this information will be given to LensCrafters by the Jaeb Center, via the EyeMed/Eye Care Plan of America website, to help process the making of your child's eyeglasses.

The information collected by the temperature sensor on your patch will be sent to a secure data server over the internet. This information may be seen by the company that makes the temperature sensor. This information includes the temperature recorded by the sensor, the date and time the temperature is recorded, and a sensor code. The information sent will not identify you to anyone at the company that makes the sensor or anyone outside of the study.

Contact from the Jaeb Center

Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you for the phone calls described earlier. Also, if your study doctor's office is not able to locate you when they try to schedule your follow-up visit, a third-party search service may be used to try to contact you. You may receive updates about the study in the mail. You may also receive updates and information about the study in the mail. A study logo item; i.e., piggy bank, tee-shirt or stuffed animal, might also be sent to you as approved by the IRB.

You may also have communication with the study doctor's office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone. Please be aware that if you email or text the study doctor's office these methods are not secure. This means that someone could see the message that is not supposed to. This would be like if your email gets hacked.

You will receive text messages from the Jaeb Center through a third-party texting service. The text messages will be sent automatically using a computer program from the Jaeb Center database. This database is designed with security protections. Your contact information will be saved in a different part of the database and will not be saved with your study information. The third-party texting service will

only receive your phone number and has agreed to only use your phone number for the study texts. These messages are secure, but you will not be able to respond to them.

Clinical Trial Reporting

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

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 take part in this study. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose to allow your child to participate, you and your child can withdraw your child at any time, and you will receive a copy of this consent form
- you authorize the use and disclosure of your child's protected health information. This information is collected as part of participation in this study. Your child cannot be in this study if you do not provide this permission.

_____ _____

LAR Signature Date

Investigator's Certification

I certify that to the best of my knowledge the LAR understands the nature, demands, risks, and benefits involved in the participation of this study.

_____

Investigator's Printed Name

_____ _____

Investigator's Signature **Date**