

Side Effects of Atropine (SEA) Study

NCT03593044

July 6, 2018

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Side Effects of Atropine (SEA) Study

Principal Investigator: Jeffrey J. Walline, OD PhD

Sponsor: The Ohio State University College of Optometry

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to determine the possible side effects of 0.01% atropine used every night for seven days. 1.0% atropine is approved by the United States Food and Drug administration, and it is typically used to make the pupil of the eye bigger or to decrease the ability to focus the eye for long periods of time. It is available only by a prescription. The risks of atropine when used for these purposes are well known, but this study will evaluate the side effects when it is given in a much lower dose and used for a different purpose.

2. How many people will take part in this study?

Up to 40 people will participate in this study.

3. What will happen if I take part in this study?

If you take part in this study, you will come to two visits, a week apart, for less than one hour each time. In between visits, you will put 0.01% atropine eye drops in both eyes every night. During each of the visits, we will measure your vision, pupil size, eye focusing, reading speed, eye pressure, and ask you about your vision and eye comfort

4. How long will I be in the study?

There are two visits, one week apart. The first visit lasts about one hour, and the second will be shorter.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your grades or your relationship with The Ohio State University or the College of Optometry.

6. What risks, side effects or discomforts can I expect from being in the study?

0.01% atropine may cause blurry vision or light sensitivity, or the drops may sting slightly for a short time when put in the eyes. If you experience blurry vision at near, we will provide you with glasses to improve your vision. If you experience light sensitivity, we will provide you with disposable sunglasses.

7. What benefits can I expect from being in the study?

You will not gain any individual benefits by being in the study, but you will help us understand what side effects to expect if taking 0.01% atropine on a daily basis.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs for taking part in this study.

10. Will I be paid for taking part in this study?

By law, payments to subjects are considered taxable income. You will receive \$10 cash for each visit attended. You will also receive a free parking pass if necessary.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
 - working for or with the sponsor; or
 - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- Others: *Jeffrey J. Walline and Ben Cyphers*.

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact *Jeffrey J. Walline: walline.1@osu.edu* or 614-247-6840.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact *Cathy Beatty: beatty.22@osu.edu* or 614-247-6190.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact *Jeffrey J. Walline: walline.1@osu.edu* or 614-247-6840.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form.

Printed name of subject	Signature of subject	
		AM/PM
	Date and time	
Printed name of person authorized to consent for subject (when applicable)	Signature of person authorized to consent for subject (when applicable)	
		AM/PM
Relationship to the subject	Date and time	

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	Signature of person obtaining consent	
		AM/PM
	Date and time	

Witness(es) - May be left blank if not required by the IRB

Printed name of witness	Signature of witness	
		AM/PM
	Date and time	
Printed name of witness	Signature of witness	
		AM/PM
	Date and time	