Augmented Macular Pigment Supplement and Pericentral Visual Function: A Randomized Controlled Trial

NCT #: Not yet assigned

Date: 17 December 2020

Subject Consent to Take Part in a Study of
VISUALL-3: A VISUAL ACUITY VALIDATION STUDY
University of the Incarnate Word
Baptist Medical Center Glaucoma Service
Vanderbilt University

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Key Information: Your consent is being sought for a research study. The purpose of the research is to validate a new device for vision testing. If you agree to participate in this study, the project will involve:

- Taking an oral supplement (or placebo) that contains nutrients that might improve your vision
- 4 visits are required
- Each visit will be approximately 1 hour long and will involve testing:
    - Contrast Sensitivity
    - Density of macular pigments
    - Skin macular pigment levels (Veggie Meter)
    - At your final visit you will do a visual field test
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- There are minimal risks associated with this study
- You will not be paid for your participation
- Your participation is voluntary and you may decide not to participate at any time

Invitation: You are invited to volunteer as one of 24 subjects in the research project named above. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

Why are you being asked to be in this research study? You are being asked to be in this study because you are an adult with glaucoma with good eye pressure control but you still appear to be losing vision on the visual field test.

What is the reason for doing this research study? The purpose of this study is to see if there is any improvement in visual function or measurements of macular pigments in your skin and eye. Macular pigments are nutrients that are important for protecting your eye from harmful light. The supplement we are asking you to take contains these nutrients.

What will be done during this research study? We will randomly assign you to receive Lumega-Z (supplement with macular pigments) or a placebo (a similar drink without active ingredients) and then test to see how taking the supplement or placebo affects nutrient levels in your skin and eye. We will also test how well you can identify contrast, and how your visual field may be affected.

This study is not part of your health care.

How will my data/samples/images be used? Your specific data could be used for future research studies. You are given the option to choose whether you will allow your deidentified data to be stored indefinitely for further analysis or other relevant research studies.

Will I be notified if my data result(s) in an unexpected finding?
When specific data are collected and analyzed, there is a chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is needed).

In this study, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your data. The results from the data we collect in this research are not the same as what you would receive as part of your health care. The data will be reviewed by a physician who normally reads such results and if there are any unexpected findings and we will provide you with this information so that you may discuss it with your personal physician. If you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your personal physician.

What are the possible risks of being in this study? There are minimal risks to you from being in this research study.

-Minor pain or discomfort: the Veggie will squeeze your index finger and the eye drop may cause some minor discomfort. It is usually not severe enough to warrant stopping the drop. Please lt us know if the drop causes severe burning or pain.

-COVID-19: we exceed CDC recommendations in order to ensure you are safe while you are at the office

What are the possible benefits to you? It is possible that the supplement you take will cause a small improvement in vision, but it is also possible that nothing will happen.

What are the possible benefits to other people? The potential benefits of taking a supplement like Lumega-Z are not yet fully known. If we find that it is beneficial for glaucoma patients, many patients with glaucoma may start taking the medication and also benefit.

What are the alternatives to being in this research study? Instead of being in this research study you can choose not to participate.

What will being in this research study cost you? There is no cost to you to be in this research study.

Will you be compensated for being in this research study? You will not be paid for your participation in this research study.

How will information about you be protected? Everything we learn about you in the study will be confidential. The only persons who will have access to your research records are the study personnel, the

Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. If we publish with results of the study, you will not be identified in any way.

What will happen if you decide not to be in this research study or decide to stop participating once you start? You can decide not to be in this research study, or you can stop being in this research study at any time, for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with the University of the Incarnate Word or Baptist Medical Center Glaucoma Service. You will not lose any benefits to which you are entitled.

What should you do if you have a problem or question during this research study? If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

If you have any questions now, feel free to ask us. If you have additional questions about your rights or wish to report a problem that may be related to the study, please contact the University of the Incarnate Word Institutional Review Board office at 210-805-3036 or 210-805-3565.

Consent for future use of data: Initial one of the following to indicate your choice:

_____I give permission for my deidentified data to be used in the future for additional analysis or other relevant research studies. I understand that no additional informed consent for this use will be sought. I understand that my deidentified data can be stored indefinitely.

_____I give my permission for my data to be used for this research study only. I do not give permission for any future use beyond the scope of this research study. I understand that my data will be destroyed within 2 years after completion of this study.

Consent
Your signature indicates that you (1) consent to take part in this research study, (2) that you have read and understand the information given above, and (3) that the information above was explained to you, and you have been given the chance to discuss it and ask questions. You will be given a copy of this consent form to keep.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of Principal Investigator/Designee

_____ _____
Signature of Principal Investigator/Designee Date

UIW IRB APPROVED
Approval #: 20-11-005
Date Approved: 11/17/2020