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Effect of Lutemax 2020 on blue light and visual health markers

Submission date	Recruitment status	[_] Prospectively registered
23/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/08/2019	Eye Diseases	

Plain English summary of protocol

Background and study aims

In the retina (the layer at the back of the eye which is sensitive to light), there is a yellow pigment called macular pigment. This pigment is made up of three carotenoids (lutein, zeaxanthin and meso-zeaxanthin). These carotenoids are obtained from the diet and are thought to be important for preserving and improving vision. This study is going to look at the relationship between macular carotinoids and visual function in order to find out if taking a supplement called Lutemax 2020 (which contains lutein and zeaxanthin) can help to improve contrast sensitivity, visual processing and glare sensitivity.

Who can participate?

Adults aged between 18 and 25 who are exposed daily to high energy sources such as UV, blue light and electronic devices such as TV, computer , IPAD and cell phones for at least more than four hours per day.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group take a capsule of Lutemax 2020, which contains 20 mg Lutein and 4 mg Zeaxanthin, once a day for six months. Participants in the second group take a capsule containing safflower oil, which acts as a placebo (dummy), once a day for six months. Participants in both groups undergo a number of visual tests as well as providing a blood sample so that lutein levels can be measured. In addition, participants also complete a number of questionnaires in order to measure their general health cognitive function (thinking, processing and memory).

What are the possible benefits and risks of participating?

Participants may benefit from learning more about their own visual function and the role that macular carotinoids play. There are no significant risks involved but some participants may experience pain, bleeding or bruising following blood sample collection.

Where is the study run from?

University of Georgia (USA)

When is the study starting and how long is it expected to run for?
May 2015 to February 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BL Study I and II/

Study information

Scientific Title
Macular carotenoids and blue light: Relationships with visual performance, sleep, health, and quality of life

Study objectives
The aim of this study is to evaluate the effects of macular carotenoids on visual function tests and sleep improvement over placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Georgia Office of the Vice President for Research Institutional Review Board, 19/06/2015, ref: 00001914

Study design
Double-blind randomized placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Eye damage

Interventions
Participants are randomly allocated to one of two study groups.

Intervention group: Participants take a capsule of Lutemax 2020, which contains 20 mg Lutein and 4 mg Zeaxanthin isomers, once a day for six months.
Control group: Participants take a capsule containing a placebo (safflower oil) once a day for six months.

Participants attend study visits at baseline, 3 and 6 months.

Intervention Type
Supplement

Primary outcome measure
1. Contrast sensitivity is determined using a computer-based, 2-alternative, forced-choice procedure at baseline, 3 and 6 months
2. Glare sensitivity is measured using the disability glare performance task and the photostress recovery performance task at baseline, 3 and 6 months
3. Macular pigment optical density is assessed via heterochromatic flicker photometry at baseline, 3 and 6 months

Secondary outcome measures

1. Psychological stress is measured using the Psychological Stress Measure (PSM-9) and the Brief Symptom Inventory (BSI) at baseline, 3 and 6 months
2. Lutein concentration is measured by High-Performance Liquid Chromatography (HPLC) and Enzyme-linked Immune Sorbent Assay (ELISA) using blood samples at baseline, 3 and 6 months
3. General health status is measured at baseline, 3 and 6 months using the following:
25-item Suboptimal Health Status Questionnaire (SHSQ-25).
3.1. SCL 90-r overall affect assessment
3.2. Beck Depression Inventory
3.3. Beck Anxiety Inventory
3.4. Dietary Questionnaire
3.5. A standard cognitive battery (RBANS-update)
3.6. The Pittsburgh Sleep Quality Index (PSQI)
3.7. A questionnaire on different attributes including frequencies such as head ache, eye strain and eye fatigues will be questioned before and after supplementation

Overall study start date
02/05/2015

Completion date
03/02/2016

Eligibility

Key inclusion criteria
1. Two-three hours of outside activity per day will be recruited with preference, due to blue light exposure
2. MPOD of subjects ≤0.69
3. One or more of the following symptoms:
3.1. Accommodative issues (difficulty seeing in the distance after prolonged nearwork)
3.2. Digital eyestrain
3.3. Blurry vision
3.4. Difficulty focusing
3.5. Dry and irritated eyes
3.6. Headaches
3.7. Neck and/or back pain
4. Aged 18 to 25 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

N=45

Key exclusion criteria
1. Body Mass Index of 30 or greater
2. Macular pigment optical density (MPOD) of 0.70 or higher
3. Ocular disease or insufficient visual acuity (cut off 20/30 visual acuity)
4. Systemic disease or any chronic disease condition
5. Smokers
6. Current use of psychiatric medication

Date of first enrolment
16/05/2015

Date of final enrolment
18/06/2015

Locations

Countries of recruitment
United States of America

Study participating centre
University of Georgia
UGA Psychology Department
125 Baldwin Street
Athens
Athens
United States of America
30602

Sponsor information

Organisation
OmniActive Health Technologies Inc.

Sponsor details
67 East Park Place
Suite 500
Morristown
United States of America
07960

Sponsor type
Industry

Website
http://www.omniactives.com

ROR
https://ror.org/024e1pj18

Funder(s)

Funder type
Industry

Funder Name
OmniActive Health Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
12/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/06/2017		Yes	No
Results article	results	19/06/2018		Yes	No
	results				

Results article	01/11/2019	21/08/2019	Yes	No