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Effect of Lutemax 2020 on visual and brain health markers

Submission date	Recruitment status	[_] Prospectively registered
23/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2018	Eye Diseases	

Plain English summary of protocol

Background and study aims
Macular carotenoids are pigments essential for improving and optimising eye function. They are obtained via the diet; foods rich in carotenoids include green vegetables, such as spinach, peppers and oranges. There is also evidence to suggest that they can be beneficial for cognitive (brain) health. This study is investigating whether giving people the carotenoid lutein as a supplement (Lutemax 2020) can lead to improvements in visual and brain function. Two different doses of the supplement (10 mg and 20 mg) are compared along with a placebo (dummy pill).

Who can participate?
Healthy adults aged between 18-25 years.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in group 1 are given a placebo to take once a day for a year. Those in group 2 are given Lutemax 2020 (10mg) once a day for a year.
Those in group 3 are given Lutemax 2020 (20mg) once a day for a year. They all have visual and brain function tests before they start the study, 6 months into the study and then again at the end of the study (12 months).

What are the possible benefits and risks of participating?
Participants may learn more about their visual and cognitive functions including stress and mood and about the role of macular carotenoids. There may be some minimal risk associated with taking blood samples as part of the tests involved.

Where is the study run from?
University of Georgia (USA)

When is the study starting and how long is it expected to run for?
December 2014 to June 2016

Who is funding the study?
OmniActive Health Technologies Inc.

Who is the main contact?
Dr Vijaya Juturu

Contact information

Type(s)
Scientific

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Protocol serial number
LAMA STUDY II /STUDY00000711

Study information

Scientific Title
Lutein and Mental Acuity Study II: an assessment of lutein and systemic factors that impact cognitive function

Study objectives
This study is to see the effect of Lutemax 2020 (L/Zi) at 10 and 20 mg over placebo on visual and brain health markers. Lutein supplementation studies have demonstrated an increase in macular pigment optical density (MPOD) and this study will show relationship of increase in MPOD may have an effect on brain health markers. This study also may provide us the dose effect on visual and brain health markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Georgia Office of the Vice President for Research Institutional Review Board, 19/03/2014, ref: LAMA STUDY II /STUDY00000711

Primary study design
Interventional

Study design
Double-blind, placebo controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Age-related macular degeneration

Interventions
This is a double blind placebo controlled trial having three arm parallel study. Subjects were randomized by blocks and the following supplementation was administered one capsule per day. Total duration of treatment: one year.

Treatment arms : Placebo, 10 mg Lutemax 2020 (10 mg L and 2 mg Zeaxanthin isomers) and 20 mg Lutemax 2020 (20 mg L and 3 mg Zeaxanthin isomers)

Before supplementation (baseline), 6 months and at 12 months visual markers such as MPOD, Contrast sensitivity, disability glare and photostress recovery time will be measured and brain health markers will be assessed based on questionnaires.

Intervention Type
Supplement

Primary outcome(s)
1. Macular Pigment Density (MPOD), assessed via heterochromatic flicker photometry
2. Contrast sensitivity (at 8 cycles / degree), determined with a computer-based, 2-alternative, forced-choice procedure
3. Disability glare - this visual performance task involves determining a subject's ability to see "through" glare produced by lights presented in the periphery. The experimental apparatus is a ring of white LED lights through which the subject will look and attempt to identify the orientation of a black and white grating stimulus (either tilted left, right, vertical, or horizontal). The intensity of the LEDs will be gradually increased (via computer control) until the subject indicates the s(he) can no longer determine the orientation of the grating. The grating will be presented on a computer screen, and flashed every 500 milliseconds, with the orientation randomize
4. Photostress recovery time - this task will assess the visual recovery time elapsed after a subject is exposed to a relatively bright light for 3 seconds. The experimental apparatus will be a solid disk of white LEDs that, when illuminated, will appear circular and subtend approximately 5 degrees of visual angle. The subject will be instructed to look at the disc of light for 3 seconds, and then indicate when s(he) can detect the orientation of a grating stimulus

Assessed at baseline, 6 months and at 12 months

Key secondary outcome(s)
1 Cognitive function using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)
2. Overall affective state, measured using the SCL 90-r overall affect assessment

3. Diet, measured using a dietary questionnaire - a brief questionnaire concerning participants' dietary intake of foods that contain lutein will be administered during each visit
4. Mood, measured using the Beck Depression Inventory - a commonly-used and validated paper-and-pencil assessment of a person's state of mood over the past few months
5. Overall health, measured using the Suboptimal Health Status Questionnaire, which assesses ambiguous health complaints, general weakness, and lack of vitality validated assessment of aspects of subject health that may be suboptimal, e.g., seasonal allergies

Assessed at baseline, 6 months and at 12 months

Completion date
05/06/2016

Eligibility

Key inclusion criteria
Participants will be asked to complete a short questionnaire to determine eligibility for the study. Questions are related to the "exclusionary criteria" noted above (subject's smoking status, body-mass index, pregnancy status, nutritional supplementation status (esp. lutein or zeaxanthin), eye disease status, and potential digestive issues

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Body Mass Index of 27 or greater. In an overweight individual, the supplemental lutein may be deposited preferentially in adipose tissue, and not in the retina
2. Macular pigment optical density (MPOD) of 0.70 or higher. Individuals with very high MPOD may be approaching saturation levels, and therefore not exhibit changes reflective of lutein supplementation. They would therefore be excluded from the study. The 0.70 criterion is a level from which subjects can typically increase appreciably upon supplementation
3. Ocular disease or insufficient visual acuity. Subjects will undergo an initial visual screening, and if either of these situations is evident, the subject will be excluded from the study. Visual acuity of 20/30 best corrected is cutoff for exclusion
4. Systemic disease. If a subject is currently in a disease state (e.g. diabetes), then s(he) will be precluded from participating the study
5. Smoking status. Current smokers will be excluded from the study. Smoking has been shown to have deleterious systemic health effects, and (germane to our proposal) is inversely related to MPOD level. The ability of smokers to accumulate supplemented lutein in the retina could be compromised
6. Psychiatric medication. Individuals currently taking medication to treat a psychiatric condition (e.g. obsessive-compulsive disorder) will not be enrolled in the study

Date of first enrolment
06/10/2014

Date of final enrolment
08/11/2014

Locations

Countries of recruitment
United States of America

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

Sponsor information

Organisation
OmniActive Health Technologies Inc

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

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	11/11/2016		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	01/05/2018		Yes	No