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Effects of three levels of macular carotenoid supplementation on macular pigment optical density, psychological stress levels, and overall health

Submission date
31/07/2015

Recruitment status
No longer recruiting

Registration date
24/08/2015

Overall study status
Completed

Last Edited
31/07/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Given the many benefits of a diet rich in lutein, and relatively high amount of lutein in the body tissues, a pressing question going forward involves the response kinetics of people to different levels of lutein in their diet; in other words, the development of reliable dose for lutein would enable us to better understand dietary need and its relationship to health and performance benefits. Moreover, given that lutein crosses the blood-brain barrier (where it appears to benefit brain function), and interacts with the immune system (as an anti-inflammatory agent), then an increased amount of lutein and zeaxanthin isomers could plausibly impact overall health, and perhaps have psychological benefits. This study seeks to address these questions.

Who can participate?
Healthy adults aged 18-25, who are non-smokers and at a healthy weight.

What does the study involve?
Participants are randomly allocated into one of four groups. Those in group 1 are given a placebo. Those in group 2 are given 6mg of lutein and 1.2mg zeaxanthin isomers (Zi). Those in group 3 are given 10mg of lutein and 2mg Zi. Those in group 4 are given 20mg of lutein and 4mg Zi. Each participant is asked to give a sample of blood (after fasting) and undergo a macular pigment optical density assessment at the start of the study and then every 2 weeks for the duration of the study (12 weeks).

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
March 2014 to February 2015

Who is funding the study?
OmniActive Health Technologies Inc (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LAMA STUDY I

Study information

Scientific Title
Effect of macular carotenoid supplementation on macular pigment optical density, psychological stress levels and overall health status

Study objectives
Given the many benefits of a diet rich in lutein, and relatively high tissue densities of lutein, a pressing question going forward involves the response kinetics of people to different levels of lutein ingestion; in other words, the development of reliable dose/response curves for lutein would enable us to better understand dietary need and its relationship to health and performance benefits. Moreover, given that lutein crosses the blood-brain barrier (where it appears to confer cognitive benefit), and interacts with the immune system (as an anti-

inflammatory agent), then increased systemic lutein and zeaxanthin isomers could plausibly impact overall health, and perhaps psychological variables such as stress. Our study seeks to address these questions.

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: STUDY00000711

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Effect of lutein supplementation

Interventions
1. Placebo
2. Lutein 6 mg, zeaxanthin isomers (Zi) 1.2 mg
3. Lutein 10 mg, Zi 2 mg
4. Lutein 20 mg, Zi 4 mg

Intervention Type
Supplement

Primary outcome(s)
1. MPOD, assessed with a non-invasive, perceptual task called customized heterochromatic flicker photometry (cHFP; Stringham et al. 2008). A densitometer (Macular Metrics Corp., Rehoboth, MA) described by Wooten et al. (1999) was used for this purpose. Measurements were taken at baseline and every 2 weeks over the 12-week study period. We obtained spatial profiles of MPOD at each visit, with measures at 10 degrees, 20 degrees, 30 degrees, 1.75 degrees, and 2.75 degrees of retinal eccentricity.
2. Psychological stress and overall health status
2. Cortisol

Measured at baseline and every two weeks over a 12-week period

Key secondary outcome(s)
1. Oxidative stress
2. Inflammation
3. Macular carotenoids
4. Brain health markers

Measured at baseline and every two weeks over a 12-week period

Completion date
20/02/2015

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Aged 18-25 years
3. Subjects willing to sign consent form
4. Subjects willing to participate for 3 month study
5. Non smoker
6. Normal BMI

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
All

Key exclusion criteria
1. Body Mass Index of 27 or greater
2. Macular pigment optical density (MPOD) of 0.70 or higher
3. Ocular disease or insufficient visual acuity
4. Subjects who have chronic or systemic disease
5. Current smokers
6. Subjects who are on psychiatric medication

Date of first enrolment
19/03/2014

Date of final enrolment
19/04/2014

Locations

Countries of recruitment
United States of America

Study participating centre
The 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	13/05/2016		Yes	No
Results article	results	01/10/2016		Yes	No
Results article	results	11/11/2016		Yes	No