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The efficacy of different nutritional formulas of lutein, zeaxanthin, and meso-zeaxanthin and their impact on the human body

Submission date
14/07/2020

Recruitment status
No longer recruiting

Registration date
30/07/2020

Overall study status
Completed

Last Edited
25/08/2020

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
Macular carotenoids are important nutrients that accumulate inside the eye, in the centre of the retina (macula). They have an important role in preserving vision since they protect against light-induced oxidative damage and can improve visual performance. Macular carotenoids have also been found in other areas of the body, like the brain. Studies have also shown they can improve certain cognitive domains such as memory, and they have been used as antioxidants in cardiometabolic diseases (i.e. heart attack, atherosclerosis, etc). Macular carotenoids are dietary of origin, which means that the human body cannot make them and their only source is from certain fruits and vegetables. The supplements used in this study are considered a major source of them, since they contain natural extracts of macular carotenoids obtained from marigolds. The aim of this study is to investigate the impact on the human body of different carotenoid formulations in nutritional supplements by measuring response in serum (blood) concentrations, as well as change in macular pigment, visual function, cognitive function, and metabolism.

Who can participate?
Healthy volunteers, between 18 and 60 years old

What does the study involve?
Participants are asked to take either a supplement containing the macular carotenoids with or without fish oil, or a placebo (dummy tablet) on a daily basis for 6 months; participants are assigned to one of six different groups and neither the participants nor the investigators will know if they are consuming the supplement or the placebo until the end of the study. Each participant will attend the Nutrition Research Centre Ireland, Waterford Institute of Technology, West Campus, Carriganore, Waterford, for three study visits over a 6-month period. There are two main visits, at the start (first visit) and at the end (last visit) of the trial, and a short visit at month 3 only for a fasting blood sample. The main visits last about 2 hours 30 minutes, whereas the study visit for blood samples lasts no more than 10 minutes.

What are the possible benefits and risks of participating?
The researchers draw a fasting blood sample and perform ocular dilation in one eye; however,

no risks to participants are foreseen. Participation in this study is not a substitute for standard medical care or eye care. It is anticipated that society will benefit from this study. At the end of the study, the researchers will provide a full report on the evaluations performed to you. The participant will be given feedback and gain knowledge on their vision status, cognitive evaluation and macular pigment levels as well as nutritional information and general health recommendations. They will be informed on their macular pigment, which is of note as research has suggested that a person's macular pigment level is a good indicator of overall eye health and brain function.

Where is the study run from?
Waterford Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?
April 2017 to December 2018

Who is funding the study?
Waterford Institute of Technology Co-Fund Scholarship: Nutrition Research Centre Ireland, Waterford Institute of Technology and Enterprise Partner: Industrial Organica (Mexico)

Who is the main contact?
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Contact information

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Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact of formulation on lutein, zeaxanthin, and meso-zeaxanthin bioavailability: a randomized double-blind placebo-controlled study

Acronym
COAST (the Carotenoid-Omega bio-Availability STudy)

Study objectives
The hypotheses were (a) that the active intervention groups (unrelated treatments) would all have a higher average response, after 6 months, in serum and in tissue concentrations compared with the placebo group, and (b) that the diacetate intervention would have a higher average response as compared with the other three active intervention groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/05/2017, Research Ethics Committee of Waterford Institute of Technology (Waterford, Ireland; +353 (0)51 302000; ethics@wit.ie), ref: 17/HS-MPRG/01

2. Approved 24/05/2017, Research Ethics Committee of the HSE, South Eastern Area (Waterford Regional Hospital, Waterford, Ireland; +353 (0)51 842026; caroline.lamb2@hse.ie), ref: not provided

Study design
Six-arm intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
The impact of formulation on lutein, zeaxanthin, and meso-zeaxanthin bioavailability in a healthy Irish adult sample

Interventions
Participants were blocked randomized, with equal probability and separately for men and women, to one of five active intervention groups, or to a placebo group. Block randomization was performed using a trial management system, “Trial Controller”, designed by the research group. Participants take on a daily basis for 6 months:

Group 1: lutein (L) (10 mg) + meso-zeaxanthin (MZ) (10 mg) + zeaxanthin (Z) (2 mg) provided in one capsule
Group 2: L (10 mg) + MZ (10 mg) + Z (2 mg) provided in two capsules
Group 3: L (10 mg) + MZ (10 mg) + Z (2 mg) provided in DHA/EPA (430 mg/ 90 mg) in two capsules
Group 4: L (10 mg) + MZ (10 mg) + Z (2 mg) diacetates provided in micromicellar formulation in one capsule
Group 5: L (5 mg lutein) = MZ (15 mg) + Z (1 mg) provided in 1 g of fish oil in two capsules
Group 6: placebo (sunflower oil)

Neither the participants nor the investigators will know if they are consuming the supplement or the placebo until the end of the study.

Each volunteer will attend the Nutrition Research Centre Ireland, Waterford Institute of Technology, West Campus, Carriganore, Waterford, for three study visits over a 6-month period. There are two main visits, at the start (first visit) and at the end (last visit) of the trial, and a short visit at month 3 only for a fasting blood sample. The main visits last approximately 2 h 30 min, whereas the study visit for blood samples lasts no more than 10 minutes.

Intervention Type
Supplement

Primary outcome measure
Lutein, zeaxanthin, and meso-zeaxanthin bioavailability measured in serum, macular pigment, and skin using high-performance liquid chromatography (HPLC), the Spectralis investigational macular pigment optical density (MPOD) module, and the Nu Skin Pharmanex S3 scanner, respectively, at baseline and 6 months

Secondary outcome measures
1. Serum lipid concentrations measured from a blood sample using mass spectrometry at baseline and 6 months
2. DHA and EPA measured from a blood sample using gas chromatography at baseline and 6 months
3. Visual function measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) logarithm of the minimum angle of resolution (LogMAR) chart (Test Chart 2000 PROTM) for Best-corrected visual acuity (BCVA); the LogMAR EDTRS (Test Chart 2000 PROTM) for Letter Contrast Sensitivity (CS); the “Advanced Vision and Optometric Tests” (AVOT) for visual acuity, contrast sensitivity, cone and rod vision; at baseline and 6 months
4. Cognitive function measured using tests of attention, memory, executive function and decision making from the Cambridge Neuropsychological Test Automated Battery (CANTAB, Cambridge Cognition, UK) at baseline and 6 months
5. Medical information obtained through a questionnaire and physical examination at baseline and 6 months

Overall study start date
01/04/2017

Completion date
19/12/2018

Eligibility

Key inclusion criteria
1. Healthy adults
2. Age group between 18 and 65 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

96

Total final enrolment
97

Key exclusion criteria
1. A medical diagnosis of a critical or acute medical condition
2. Intake of nutritional supplements containing lutein, zeaxanthin, meso-zeaxanthin or omega-3 fatty acids

Date of first enrolment
01/09/2017

Date of final enrolment
03/07/2018

Locations

Countries of recruitment
Ireland

Study participating centre
Nutrition Research Centre Ireland
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
Industry

Funder Name
Industrial Organica

Funder Name
Waterford Institute of Technology

Results and Publications

Publication and dissemination plan
Primary outcomes will be published in an initial publication in a high-impact peer-reviewed journal, followed by subsequent publications focused on secondary outcomes.

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/08/2020	25/08/2020	Yes	No