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Effects of lutein and omega-3 fat enriched egg consumption on visual function in older adults: Implications for age-related macular degeneration

Submission date
25/06/2018

Recruitment status
No longer recruiting

Registration date
28/06/2018

Overall study status
Completed

Last Edited
27/06/2018

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Despite ample research showing the ability of lutein, zeaxanthin and omega-3 docosahexaenoic acid (DHA) to benefit retina (eye) function, research using whole foods as a vehicle for these nutrients is lacking. As age-related macular degeneration (AMD) is common among Caucasian older adults, this study investigates whether DHA-enriched egg consumption can improve retina function in this population.

Who can participate?
Healthy Caucasian adults aged 50-80

What does the study involve?
Participants consume two lutein and DHA enriched eggs daily for six weeks, while avoiding supplements and foods high in eye-related nutrients. Rod and cone (eye) cell function is assessed by full field electroretinogram (an eye test). Blood DHA, lutein and lipid levels are measured at the start of the study and after 6 weeks.

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

Where is the study run from?
Richardson Centre for Functional Foods and Neutraceuticals (Canada)

When is the study starting and how long is it expected to run for?
May 2013 to September 2014

Who is funding the study?
1. Agri-Food Research and Development Initiative's (ARDI) Growing Forward program
2. Manitoba Egg Farmers
3. Burnbrae Farms Inc.

Who is the main contact?
Mrs Chelsey Walchuk
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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
J2013:104

Study information

Scientific Title
Effects of lutein and docosahexaenoic acid enriched egg consumption in older adults: Implications for age-related macular degeneration

Acronym
Egg and Vision Study

Study objectives
Lutein and DHA enriched egg consumption will improve retina function in Caucasian older adults by increasing egg-nutrient associated blood profiles while not adversely affecting plasma lipid profiles. More specifically, in Caucasian older adults, lutein and DHA enriched egg consumption will:

1. Improve self-assessed health and vision status
2. Improve electrophysiological retina function
3. Not influence TC and TAG concentrations
4. Not influence HDL-C/LDL-C particle size
5. Increase DHA in plasma and erythrocytes
6. Increase lutein in plasma

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manitoba Joint-Faculty Research Ethics Board, 02/08/2013, Protocol #J2013:104

Study design
Single-centre 6-week intervention trial with a repeated measure design

Primary study design
Interventional

Secondary study design
Repeated measure

Study setting(s)
Other

Study type(s)
Prevention

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
General health of the retina and prevention of age-related macular degeneration

Interventions
Avoidance of retina/eye related food items for one month prior and throughout the duration of the trial (6 weeks) including: eggs; oysters; liver (chicken, beef, veal, etc.); sweet potato; pumpkin; carrots; kale; fish and caviar; spinach; supplements that contain zinc, choline, vitamin A, lutein, zeaxanthin and DHA.
Limit retina/eye related food items for one month prior and throughout the duration of the trial (6 weeks) including: pork ham, bacon, beef, lamb, butternut squash, collard greens, turnip greens, baked beans and green peas
Treatment: 2 medium (92g) lutein and docosahexaenoic acid enriched eggs (0.87 mg lutein/day, 220 mg DHA/day) daily for 6 weeks to be consumed/cooked at the discretion of the participant.
Control: No control group as participants acted as their own control from PRE to DURING and POST assessment following consumption of enriched eggs.

Rod and cone cell function was assessed by full field electroretinogram. Plasma and red blood cell (RBC) DHA, plasma lutein, lipid profiles, and lipoprotein subfractions were assessed at day 0 (PRE) and 6 wks (POST).

Intervention Type
Supplement

Primary outcome measure
1. Self-assessed health and vision status measured using a modified version of the National Eye Institute Visual Functioning Questionnaire at PRE (week 0), DURING (week 3) and POST (week 6) assessment
2. Plasma lipid profiles (Total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglycerides), measured using a Cobas C 111 Analyzer at PRE (week 0), DURING (week 3) and POST (week 6) assessment
3. Plasma fatty acids, measured by gas chromatography at PRE (week 0), DURING (week 3) and POST (week 6) assessment
4. Plasma lutein, measured using high performance liquid chromatography at PRE (week 0), DURING (week 3) and POST (week 6) assessment
5. Retina function, measured using a full field electroretinogram at PRE (week 0), DURING (week 3) and POST (week 6) assessment

Secondary outcome measures
1. Average dietary intake, measured using a 3-day food record analyzed using The Food Processor software between DURING (week 3) and POST (week 6) assessment
2. LDL/HDL particle size, measured using polyacrylamide gel electrophoresis (Lipoprint Lipoprotein Subfractions Testing System, Quantimetrix, California, US) at PRE (week 0) and POST (week 6) assessment

Overall study start date
01/05/2013

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Individuals between 50-80 years of age
2. Caucasian ethnicity
3. Good English written and oral communication skills

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
30

Key exclusion criteria

1. Individuals with an egg allergy
2. Individuals diagnosed with a chronic disease (ie. diabetes, cardiovascular disease etc)
3. Individuals diagnosed with mental cognitive disorders
4. Individuals diagnosed as hypercholesterolemic
5. Individuals taking statins and other lipid lowering medications
6. Individuals diagnosed with eye related disease (i.e. glaucoma, AMD, retinitis pigmentosa, etc)

Date of first enrolment
01/07/2013

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Canada

Study participating centre
Richardson Centre for Functional Foods and Neutraceuticals
196 Innovation Drive
University of Manitoba, SmartPark
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Sponsor information

Organisation
University of Manitoba

Sponsor details
66 Chancellors Circle
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R3T 2N2

Sponsor type
University/education

Website
http://umanitoba.ca/

ROR
https://ror.org/02gfys938

Funder(s)

Funder type
Research organisation

Funder Name
Agri-Food Research and Development Initiative’s (ARDI) Growing Forward program

Funder Name
Manitoba Egg Farmers

Funder Name
Burnbrae Farms Inc.

Results and Publications

Publication and dissemination plan
1. The full electronic thesis for the proposed research can be obtained from http://hdl.handle.net/1993/32212
2. The trial is to be ready and submitted for publication July 2018

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Miyoung Suh (miyoung.suh@umanitoba.ca) and Chelsey Walchuk (umwalchu@myumanitoba.ca).

IPD sharing plan summary
Available on request