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Egg Xanthophyll Interventional Trial

Submission date
14/06/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
09/08/2013

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
There is a yellow pigment at the back of the eye (retina) called macular pigment which is believed to be important for improving visual performance and visual comfort. Macular pigment is of dietary origin, i.e. we are not born with macular pigment but we accumulate it from eating certain fruits and vegetables. Eggs are also a major source of macular pigment. This study is designed to test the benefits of egg consumption on macular pigment levels and vision.

Who can participate?
Thirty healthy volunteers between the age of 18-60 years with normal cholesterol levels will be eligible to take part in this study.

What does the study involve?
Volunteers will be randomly allocated to one of five groups. Volunteers in the four intervention groups will be provided with eggs containing different amounts of the macular pigments, and volunteers in the control group will receive normal non-enriched eggs, to be taken daily for the duration of the study. Each volunteer will visit the study centre on two separate occasions: at the first visit at the start of the study and after two months of eating the eggs. Each study visit will last about two hours. They will be asked to eat a meal containing two eggs each day for eight weeks in total. During the study visit, a blood sample will be taken to measure macular pigment and cholesterol levels in the blood. They will be asked to complete a short questionnaire to gather information that might be important to the status of the eye. A picture of the back and front of the eye will be taken using a specialised camera. They will be asked to fill in a dietary questionnaire, which will find out the macular pigment levels in your diet. They will be required to undergo brain function testing by following simple on-screen instructions on a touch screen computer.

What are the possible benefits and risks of participating?
You will gain knowledge of your macular pigment level. It has been suggested that a persons macular pigment level is a good indicator of overall eye health. This will be provided at the end of the study. Also, it is possible that society may gain from the results of this study. The brain function test is a non-invasive test and will be achieved using standardised and appropriate memory and reaction tests. We foresee no risks to the subjects participating in this study. However, eggs contain high amounts of cholesterol and therefore a high egg intake (such as in this study) may potentially have a negative impact on subjects with high levels of blood

cholesterol. The eggs will be produced in accordance with appropriate food quality standards. However, in the unlikely event that you feel unwell as a result of having the egg at any stage of the study, we would ask you to contact the researcher listed below, who will then follow the appropriate procedures.

Where is the study run from?
The study is run from Carriganore House, West Campus, Waterford Institute of Technology, Ireland.

When is the study starting and how long is it expected to run for?
The study will commence in September 2013 and will be active for 3 months in total.

Who is funding the study?
This study is sponsored by Nutrasight Consultancy Ltd, a local research company located at Arclabs, Waterford Institute of Technology, Ireland.

Who is the main contact?
Ms Katie Meagher
kmeagher@wit.ie

Contact information

Type(s)
Scientific

Contact name
Prof John Nolan

Contact details
Waterford Institute of Technology
Carriganore House
West Campus
Carriganore
Waterford
Ireland
Waterford
Ireland
N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Egg Xanthophyll Interventional Trial: a randomised controlled study

Acronym
EXIT

Study objectives
The aim of this study is to measure serum, macular and cognitive responses to supplementation with lutein (L), zeaxanthin (Z) and meso-Z (MZ) fortified eggs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial was approved by the Waterford Institute of Technology Ethics committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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
Age-related macular degeneration

Interventions
Volunteers will be provided with eggs containing different amounts of the macular pigments, or a normal non-enriched egg, to be taken daily for the duration of the study. They are randomised to 5 groups. Fortified eggs will be used as supplements as follows:
Group 1: L fortified egg
Group 2: MZ fortified egg
Group 3: Egg with 1:1 ratio of MZ and L
Group 4: Z fortified egg
Group 5: Standard egg (control egg)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Macular pigment response: measured using the Spectralis OCT (Heidelberg Engineering); cognitive function is measured using CANTAB interactive software (Cambridge Cognition). All measurements will be made for each study visit. Study visits will be completed at baseline and at the end of the trial (week 8).

Secondary outcome measures
Serum carotenoid response: measured using high performance liquid chromatography (HPLC)

Overall study start date
16/09/2013

Completion date
30/11/2013

Eligibility

Key inclusion criteria
Eligible subjects will have no ocular pathology, no history of cardiovascular disease, no allergy to egg-containing products, low cholesterol and non-smoking status.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
Subjects will only be eligible if they have no recent history of supplementation with the macular carotenoids, or cholesterol-lowering statins.

Date of first enrolment
16/09/2013

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
Ireland

Study participating centre
Waterford Institute of Technology
Waterford
Ireland
N/A

Sponsor information

Organisation
The Howard Foundation (UK)

Sponsor details
c/o HFH Group
PO Box 1187
Cambridge
United Kingdom
CB22 5WB

Sponsor type
Charity

ROR
https://ror.org/03ywwjy69

Funder(s)

Funder type
Charity

Funder Name
The Howard Foundation, UK

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration