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The effect of the dietary antioxidant supplements lutein and zeaxanthin on retinal macular pigment optical density

Submission date
14/12/2011

Recruitment status
No longer recruiting

Registration date
10/02/2012

Overall study status
Completed

Last Edited
08/08/2016

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and aims
Age-related macular degeneration (AMD) the breakdown of the macular pigment (MP) in the retina of the eye is the most common cause of blindness in the developed world. MP is an accumulation in the retina of two hydroxycarotenoids, lutein (L) and zeaxanthin (Z), which human beings can only derive from their diet. Previous studies suggest that an increase in L/Z decreases AMD risk, and various formulations of L and Z supplement are already being marketed as improving eye health. However, studies investigating the effects of dietary change and supplements on MP density have shown a range of responses, with some subjects MP density increasing up to 40% and others remaining unchanged. The aim of this study was to investigate the effects of a high-dose L and Z supplement on MP levels in twins. By studying identical and non-identical twins, we also hope to determine whether MP change in response to supplementation is genetically passed on.

Who can participate?
Participants were female, aged 16-50, and enrolled on the TwinsUK adult registry we needed to recruit both identical and non-identical twin pairs. We looked for healthy volunteers rather than participants with a certain condition.

What does the study involve?
Macular pigment optical density (the amount of macular pigment) was measured using two methods: heterochromatic flicker photometry (HFP) and two-wavelength fundus autofluorescence (AF).
The HFP measurement was carried out using a compact, portable instrument called a Maculometer. This was placed on a tabletop, and participants were asked to rest their forehead against a guide and look through an opening at a target, which was a flickering light. They were then asked to turn a dial controlling the amount of flicker until the light stopped flickering (or until the amount of flicker was at its lowest). They were given a couple of chances to practise, and the test was then repeated five times. The target then changed to a dim red spot surrounded by a ring of flickering light, and the test was again repeated five times. They were then asked to repeat the entire process using the other eye.

Once they had completed the HFP test, an eye drop (tropicamide 1%) was given to dilate their eyes for the AF test, which took place in a darkened room. They had to wait 20-30 minutes for the tropicamide to take effect before the AF test could begin. The right eye was then scanned twice using a laser ophthalmoscope.
In addition to the two eye tests, particpants were asked to complete two questionnaires, one on their zygosity (whether they are an identical or a non-identical twin) and one on their food consumption over the last three months. We also took a blood sample to measure levels of lutein and zeaxanthin.
Participants were then asked to take a dietary supplement called Macuvite (Springfield®) every day with food for a period of six months. Macuvite contains 18 mg lutein and 2.4 mg zeaxanthin (derived from marigold flowers and microalgae). Their normal diet was continued while taking the supplement.
They were then asked to return to the hospital for two more visits, three months and six months after starting to take the dietary supplement. The HFP and AF tests were repeated on each visit, and another blood sample was taken on their three-month visit. They were asked to bring their Macuvite pills with them on their three- and six-month visits so a pill count could be carried out. All participants received the same treatment.

What are the possible benefits and risks of participating?
It is possible that taking the dietary supplement could lead to an increase in your macular pigment optical density, but we cannot say this for certain until we have completed this and further research studies. There are no known risks to participants.

Where is the study run from?
It was organised by King's College Londons Department of Twin Research, based at the St Thomas Hospital campus, UK.

When is the study starting and how long is it expected to run for?
March 2004 to August 2005

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Professor Chris Hammond
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Macular pigment response to supplemental lutein and zeaxanthin: a twin heritability study

Study objectives
Dietary antioxidant supplements have been shown to have a beneficial effect on the clinical course of age-related macular degeneration (AMD), which is the commonest cause of blindness in the developed world. Of the various antioxidants, lutein (L) and zeaxanthin (Z) are of particular interest because of their biochemical, optical and anatomic properties.

The aim is to assess the effect of a high-dose L and Z supplement on the concentration of these nutrients at the target tissue (the macula) in a large group of healthy monozygotic and dizygotic twins and to determine the heritability of MP augmentation/change in response to supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Research Ethics Committee, 25/06/2002, ref: EC02/102

Study design
Interventional non-randomised non-placebo-controlled supplement single-centre study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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 (AMD)

Interventions
All participants asked to take daily macular pigment supplement with food, Macuvite (Springfield®), consisting of 18mg lutein (in its free form) and 2.4mg zeaxanthin (derived from marigold flowers and microalgae) for 6 months, whilst continuing normal diet. Supplement taken in pill form. No control group.

Intervention Type
Supplement

Primary outcome measure
Heritability of response to macular pigment supplement, measured using:
1. Reverse phase high performance liquid chromatography to measure serum carotenoid levels at baseline and three months
2. Heterochromatic flicker photometry (HFP) and 2-wavelength fundus autofluorescence (AF) to measure macular pigment optical density (MPOD) at baseline, three months and six months
3. Maximum likelihood modelling using Mx programme to estimate heritability of MP response to supplementation

Secondary outcome measures
1. Relationship between central retinal thickness and MPOD, measured using:
1.1. Optical coherence tomography to measure retinal thickness
1.2. HFP and AF to measure MPOD
2. Heritability of MP in the healthy eye, measured using:
2.1. HFP and AF to measure MPOD
2.2. Maximum likelihood modelling using Mx programme to estimate heritability of MPOD

Overall study start date
07/03/2004

Completion date
15/08/2005

Eligibility

Key inclusion criteria
1. Healthy female volunteers, aged 16-50
2. Twin pairs enrolled on TwinsUK adult registry held at St Thomas Hospital London (aim to recruit 80 monozygotic and 80 dizygotic pairs)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
322

Key exclusion criteria
1. Ocular pathology
2. Gastrointestinal disease

Date of first enrolment
07/03/2004

Date of final enrolment
15/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Guy's & St Thomas' NHS Trust (UK)

Sponsor details
Research & Development Office
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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) ref: 065730

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2012		Yes	No