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Collaborative Optical Macular Pigment ASsessment Study

Submission date 05/06/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/07/2008	**Overall study status** Completed	
Last Edited 11/06/2019	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IP/2007/0778

Study information

Scientific Title
Macular pigment and its contribution to visual performance and comfort

Acronym
COMPASS

Study objectives
The macula is a specialised part of the retina, as it mediates central vision, provides sharpest visual acuity and facilities best colour discrimination. Lutein (L) and zeaxanthin (Z) are uniquely concentrated in the inner and central layers of the primate macula, where they are known as macular pigment (MP).

Age-related macular degeneration (AMD) is a disease of the macula and results in the loss of central and colour vision. AMD is the most common cause of blindness in the elderly population in the Western World. While the pathogenesis of AMD remains unclear, there is a growing consensus that cumulative short-wavelength visible light damage and/or oxidative stress play a role. MP is a short-wavelength (blue) light filter and a powerful antioxidant, and is therefore believed to protect against AMD. This "protective" hypothesis of MP has been studied in detail, and has been reported extensively in the literature. However, from a Darwinian perspective, it is unlikely that MP has evolved specifically to protect against AMD, as our increased lifespan is a recent phenomenon.

Beyond the "protective" hypothesis, a number of other theories have been put forward regarding MP function. Given that Darwinian natural selection is driven by phenotypic expression of genetic background, which confers an advantage before and until the period of procreation, it follows that the biological selectivity of MP's accumulation in the retina primarily represents an advantage in young and middle age. Since AMD is an age-related condition, seen only in persons greater than 55 years, it is doubtful that this degree of biological selectivity evolved to protect against these conditions. Indeed, from an evolutionary perspective, it is likely that the selective accumulation of L and Z at the macula confers an advantage in young and middle age and, therefore, that any such advantage of MP rests on its optical (rather than antioxidant) properties. In other words, it is likely that the primary role of MP rests on its contribution to visual performance.

These "optical" hypotheses of MP have been previously discussed and may be related to at least one of the following properties:
1. MP may enhance visual acuity by reducing chromatic aberration
2. MP may reduce visual discomfort by attenuation of glare and dazzle
3. MP may facilitate enhancement of detail by the absorption of "blue haze"
4. MP may enhance visual contrast

Unlike the "protective" hypothesis, few of the visual performance "optical" hypotheses have been empirically studied. However, some of these theories have been tested, and can be summarised as follows:
1. L/Z supplementation has been linked with improved visual function in patients with congenital retinal degenerations and with AMD
2. Visual discomfort resulting from a glare source has been shown to be much higher for short-wavelength light than for mid-or-long-wavelength light
3. Subjects with higher MP have been shown to be able to handle more short-wavelength light before an aversive response (quantified by electromicrogram [EMG] recordings of squinting) was elicited
4. Light absorption by MP has been shown to influence the amount of short-wavelength light necessary to elicit photophobia

However, all of the studies that have tested and commented upon the potential "optical" hypotheses of MP, as outlined above, should be interpreted with full appreciation of the small sample sizes in these studies.

In conclusion, while there are many interesting theories ("optical" hypotheses) suggesting that MP may play an important role in visual performance and visual comfort, empirical data are needed to test such hypotheses. In brief, therefore, a well-designed, well-powered, and properly executed technical study investigating MP's association with visual parameters and ocular comfort is truly merited. For example, does psychophysical visual performance relate to baseline MP levels? Does supplementation with L and Z enhance visual performance and/or ocular comfort? Should the answer to one or both of these questions be affirmative, the potential for market expansion will be unprecedented.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Waterford Institute of Technology Research Ethics Committee on the 12th June 2007
2. The Dublin Institute of Technology research ethics committee on the 17th August 2007 (ref: 13 /07)

Study design
Randomised, placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Enhancing vision performance and comfort

Interventions
This double blind placebo controlled study has two study arms:
1. The placebo formulation contains: lactose, cellulose, microcrystalline, magnesium stearate (core) and filmbuilding material with colorants and excipients (coating material)
2. The treatment formulation contains: two dietary compounds called lutein and zeaxanthin, carotenoids from Tagetes erecta, ascorbic acid, vitamin E acetate, selenium yeast, zinc oxide, cellulose, microcrystalline, silicon dioxide, magnesium stearate (core [actives and excipients]) and filmbuilding material with colorants and excipients (coating material)

All subjects (placebo = 60 subjects and treatment = 60 subjects) will be asked to take two tables per day for 12 months. Study visits will be at baseline, three months, six months and a 12 month exit visit. At each study visit, the following will take place: generic lifestyle questionnaire; vision questionnaire; macular pigment measurement; variety of vision performance tests (e.g. contrast sensitivity and glare recovery).

Contact for public queries:
Ms Eithne Connolly

MPRG project manager
Tel: 051 845505
Ms Connolly will answer any questions concerning the study, the procedures, and any outcomes that may appear to be related to the research.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lutein-based nutritional supplement

Primary outcome(s)
1. To determine whether a person's macular pigment optical density relates to visual performance and/or ocular comfort, measured using heterochromatic flicker photometry
2. To determine whether augmentation (through supplementation) of a person's macular pigment optical density results in enhanced visual performance and/or improved ocular comfort, measured via questionnaire and by a variety of objective vision assessment techniques

The primary and secondary outcome measures will be assessed at each study visit.

Key secondary outcome(s))
1. To determine whether changes in serum concentrations of lutein and zeaxanthin are associated with changes in macular pigment levels in normal subjects
2. To determine whether objective assessments of visual performance are associated with subjective, questionnaire based, assessments of visual performance

The primary and secondary outcome measures will be assessed at each study visit.

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Any race
2. Male or female
3. Aged 18 to 40 years
4. No presence of ocular pathology
5. Visual acuity of at least 6/18 in the study eye

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
121

Key exclusion criteria
1. Outside age range 18 to 40
2. Pregnancy
3. Presence of ocular pathology
4. Cataract

Date of first enrolment
04/08/2008

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Ireland

Study participating centre
Macular Pigment Research Group
Waterford
Ireland
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Sponsor information

Organisation
Enterprise Ireland (Ireland)

ROR
https://ror.org/023z51242

Funder(s)

Funder type
Government

Funder Name
Innovation partnership - Enterprise Ireland and Bausch & Lomb (Ireland) (ref: IP/2007/0778)

Results and Publications

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	02/03/2011	11/06/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes