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The effect of nutritional supplementation on retinal function

Submission date	Recruitment status	[ ] Prospectively registered
21/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/10/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The effect of nutritional supplementation on retinal function: a randomised controlled trial

Study objectives
Nutritional supplementation may have an effect on retinal function. A randomised controlled trial comparing those taking a nutritional supplement with a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Aston University Ethics Committee, 01/10/2008, ref: REG/06/288[1]

Study design
Single-blind single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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 disease

Interventions
Nutritional supplement (oral) containing vitamin C 150 mg, vitamin E 15 mg, lutein 12 mg, zeaxanthin 0.6 mg, copper 400 µg, zinc 20 mg, omega-3 fatty acids 1,080 mg per day for 80 weeks.

Control group: no interventions (no placebo used)

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin C, vitamin E, lutein, zeaxanthin, copper, zinc, omega-3 fatty acids

Primary outcome measure
Multifocal electroretinogram amplitudes and latencies, assessed every 20 weeks for a period of 80 weeks

Secondary outcome measures
Macular pigment optical density, assessed every 20 weeks for a period of 80 weeks

Overall study start date
01/01/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
All participants (both males and females) must be aged 18 - 80 years.

1. For early age-related maculopathy (ARM) group in either eye or both eyes:
1.1. Drusen
1.2. Drusen with hyperpigmentation
1.3. Drusen with hypopigmentation
2. For early age-related maculopathy (ARM) group and normal group in either eye or both eyes:
2.1. Best corrected visual acuity of 6/9 or better
2.2. Good central fixation (necessary for the multifocal electroretinogram [mfERG])
2.3. Clear optical media
2.4. No signs of other retinal or optic nerve disease
2.5. Good general health
2.6. No medication that affects the retina

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
120

Key exclusion criteria

1. Moderate to dense lens opacities
2. Intraocular lens
3. Corneal opacities
4. Glaucoma or ocular hypertension
5. Previous history of intraocular inflammation (e.g. uveitis)
6. Previous history of retinal detachment
7. Retinal disease
8. Previous retinal laser
9. Diabetes
10. Systemic hypertension
11. History of ocular trauma
12. Neurological disease
13. Advanced age-related macular disease (choroidal neovascularisation [CNV] or geographic atrophy [GA]) in the studied eye
14. Drugs causing retinal toxicity (chloroquine, cisplatin, oxazepam, vigabatrin)
15. Previous ocular surgery (excluding laser-assisted in situ keratomileusis [LASIK]/endothelial keratoplasty [EK])
16. Epilepsy

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aston University
Birmingham
United Kingdom
B4 7ET

Sponsor information

Organisation
Bausch and Lomb (UK)

Sponsor details

106 London House
Kingston upon Thames
Surrey
United Kingdom
KT2 6TN

Sponsor type
Industry

ROR
https://ror.org/0560gb543

Funder(s)

Funder type
Industry

Funder Name
Bausch and Lomb (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