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

Contact name

Mrs Emma Berrow

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

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 μ g, 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