ISRCTN94557601 https://doi.org/10.1186/ISRCTN94557601

The putative beneficial effects of supplemental Lutein (L) and Zeaxanthin (Z) with co-antioxidants in patients with age-related maculopathy: A pilot short term randomised controlled clinical trial of antioxidant supplementation

Submission date 01/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/07/2005	**Overall study status** Completed	
Last Edited 12/12/2012	**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
DMP628.1.03

Study information

Scientific Title

Acronym
CARMA

Study objectives
Subjects aged 50 years and older with evidence of early ARM in both eyes or advanced AMD in one eye.

The primary hypothesis is that progression from early ARM to late AMD may be delayed or prevented through supplementation with key antioxidants (vitamins, minerals and carotenoids) which are either known to be present in high concentrations in healthy neural retina/retinal pigment epithelium (RPE)/choroidal interface or are free radical scavengers and thus have potential protective roles in minimisation of oxidative stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Age-related maculopathy

Interventions
Daily oral administration of supplement - Lutein + Zeaxanthin + Vitamin E + C + Zn/Cu tablet per day (to be known as CARMA Preparation)
Control: Placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lutein, Zeaxanthin, co-antioxidants

Primary outcome(s)
The primary outcome will be retinal acuity in the study eye at 12 months of supplementation. The level of significance for changes will be set at 0.05.

Key secondary outcome(s))
1. Change in distance visual acuity (DVA) in treatment and control groups at 12 months. Similar to the primary outcome the level of significance for changes will be set at 0.05.
2. Progression of ARM based on detailed grading of stereo colour fundus images. Progression is defined as a change of at least one step in the level of severity as gauged by the appearance or an increase in (a) drusen (size, frequency and extent), (b) focal hyper or hypopigmentation (area).
3. In vivo macular carotenoid signal strength.
4. Serum markers Vitamin C, lipid soluble vitamins, cholesterol.

Data from all patients who continued supplementation for more than 12 months will be collected and analysed in order get as much information as possible regarding the changes of visual function during the duration of the study. These additional data will be analysed independently from the primary and secondary outcomes at 12 months of supplementation.

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Patient must be willing to give written informed consent, make the required study visits, and follow instructions
2. Patient must be at least 50 years of age
3. Patients may be of any race or sex
4. Two groups of ARM patients may be included
Group 1: If there is choroidal neovascularisation (CNV) or geographic atrophy (GA) in one eye, any level of ARM is permissible in the fellow eye provided visual acuity (VA) is equal to or better than logarithm of the minimum angle of resolution (logMAR) 0.3
Group 2: Clinical diagnosis of severe early ARM in at least one eye.
≥20 soft distinct or soft indistinct drusen or if fewer that 20 soft drusen, focal hyper pigmentation must be present.
Visual acuity greater than or equal to 6/12 or 0.3 logMAR in the study eye (which may be both eyes).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any retinal laser therapy in the study eye
2. In Group 1 there should be no visible choroidal neovascularisation or geographic atrophy
3. History of any unstable medical condition or life threatening conditions, for example, cancer or renal failure, that would preclude scheduled study visits or completion of the study
4. History of ophthalmic disease in the study eye (other than ARM) that would compromise the visual acuity of the study eye
5. Patients currently on supplements containing the antioxidants C, E, Zn, L and Z will be asked to discontinue them and may, after a washout period of three months, be eligible for randomisation into the study
6. History of malabsorption
7. History of psychiatric disorder, which may interfere with compliance in taking study medication or attendance for study visits
8. Patients with known allergy against one of the active ingredients or the other excipients in the study medications

Date of first enrolment
01/06/2004

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Ophthalmology and Vision Science
Belfast
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Sponsor information

Organisation
Dr. Mann Pharma GmbH, Bausch & Lomb Group (Germany)

ROR
https://ror.org/049ncrn81

Funder(s)

Funder type
Industry

Funder Name
Dr Mann Pharma, Bausch and Lomb and Chauvin Group Berlin, Germany

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	01/09/2011		Yes	No
Results article	results	01/03/2013		Yes	No
Other publications	design and methods	01/11/2008		Yes	No