

# 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

<b>Submission date</b> 01/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/12/2012	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**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**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Prevention

**Participant information sheet**

**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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/06/2004

**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 than 20 soft drusen, focal hyperpigmentation 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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

360

### **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**

Northern Ireland

United Kingdom

**Study participating centre**  
**Ophthalmology and Vision Science**  
Belfast  
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## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

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### **Sponsor type**

Industry

### **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**

### **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?
<a href="#">Other publications</a>	design and methods	01/11/2008		Yes	No
<a href="#">Results article</a>	results	01/09/2011		Yes	No
<a href="#">Results article</a>	results	01/03/2013		Yes	No