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# The effect of a lutein based nutritional supplement on non-exudative age-related macular degeneration (AMD): a double-masked randomised controlled trial

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| **Submission date**<br>20/06/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>11/09/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>11/01/2018 | **Condition category**<br>Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

The effect of a lutein based nutritional supplement on non-exudative age-related macular degeneration (AMD): a double-masked randomised controlled trial

## Study objectives
Age-related macular degeneration is the leading cause of blind registration in the developed world. One aetiological hypothesis involves oxidation and the intrinsic vulnerability of the retina to damage via this process. This has prompted interest in the role of antioxidants in the prevention and treatment of this eye disease.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved by the Aston University Human Sciences Ethical Committee.

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Age-related macular degeneration

## Interventions
The study formulation contains:
Lutein 10 mg
Vitamin C 250 mg
Vitamin E 34 mg
Vitamin A 750 µg
Zinc 10 mg
Copper 0.5 mg

## Intervention Type
Supplement

## Phase
Not Specified

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

## Primary outcome(s)
1. Distance and near Visual Acuity (VA) measured using Bailey-Lovie logMAR charts
2. Contrast sensitivity (CS) measured using a Pelli-Robson chart
3. Colour vision measured using the PV-16 quantitative colour vision test

4. Macular Mapping (MM) test
5. Eger Macular Stressometer (EMS) used to assess glare recovery
6. Fundus photographs of the macular will be assessed using colour and edge analysis software

Data collection will take place at baseline, nine, and 18 months.

### Key secondary outcome(s))
Not provided at time of registration

### Completion date
01/01/2005

## Eligibility

### Key inclusion criteria
1. Have to provide written informed consent
2. Have to be available for three visits to Aston University
3. Have to present with no ocular pathology in one eye, or no ocular pathology other than dry AMD in one eye. A cataract grading system consisting of grades one, two and three for each of cortical, nuclear, and posterior subcapsular cataracts has been developed. Participants presenting with lens opacities precluding fundus photography are excluded. Throughout the trial period, progression of any type of cataract to the successive grade will require the participant to withdraw.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### Key exclusion criteria
Exclusion criteria include type I and II diabetes because vitamin E has been shown to affect glucose tolerance and diabetic retinopathy may confound the results. Those taking Warfarin medication are excluded as zinc may decrease its absorption and activity, as are those who use nutritional supplements that potentially raise vitamin and mineral intake above safe limits. The most recent guidelines for upper limits of nutritional supplementation are set out in the UK Food Standards Agency report. Neovascular AMD and other ocular disease that could potentially interfere with the results are excluded.

### Date of first enrolment
01/07/2003

### Date of final enrolment
01/01/2005

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Neuroscience Research Institute**
Birmingham
United Kingdom
B4 7ET

# Sponsor information

**Organisation**
Aston University (UK)

**ROR**
https://ror.org/05j0ve876

# Funder(s)

**Funder type**
University/education

**Funder Name**
College of Optometrists (UK)

# 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 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Results article | | 01/04/2008 | | Yes | No |
| Protocol article | protocol | 10/10/2003 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |