ISRCTN78467674 https://doi.org/10.1186/ISRCTN78467674

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

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.aston.ac.uk/downloads/lhs/website_protocol.pdf

Contact information

Type(s)
Scientific

Contact name
Miss Hannah Bartlett

Contact details
Neuroscience Research Institute
School of Life and Health Sciences
Aston University
Aston Triangle
Birmingham
United Kingdom
B4 7ET
-
bartlehe@aston.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
159

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
England

United Kingdom

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

Sponsor information

Organisation
Aston University (UK)

Sponsor details
Neurosciences Research Institute
School of Life and Health Sciences
Aston Triangle
Birmingham
England

United Kingdom
B4 7ET

Sponsor type
University/education

Website
http://www.aston.ac.uk/

ROR
https://ror.org/05j0ve876

Funder(s)

Funder type
University/education

Funder Name
College of Optometrists (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/10/2003		Yes	No
Results article	results	01/04/2008		Yes	No