ISRCTN57556290 https://doi.org/10.1186/ISRCTN57556290

A multi-site trial of a novel nutritional supplement (taurine, omega-3 fatty acids, zinc, antioxidants, and lutein) and micro-current stimulation in the treatment of atrophic (dry) age-related macular degeneration

Submission date 27/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 25/09/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AMI-P-307-C-001

Study information

Scientific Title

Acronym
TOZAL

Study objectives
1. A novel nutritional supplement containing antioxidants and omega-3 fatty acids improves visual acuity in patients with atrophic (dry) age-related macular degeneration.
2. Micro-current stimulation in combination with a novel nutritional supplement containing antioxidants and omega-3 fatty acids improves visual acuity in patients with atrophic (dry) age-related macular degeneration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethics Committee/Institutional Review Board approvals were received in April 2004 from the University of California Irvine Medical Center and Ohio State University.

Study design
Randomised prospective investigator, subject and sponsor masked 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
Atrophic (dry) age-related macular degeneration

Interventions
Nutritional supplement for six months consisting of vitamin A 10,000 IU, beta-carotene 18,640 IU, vitamin E 200 IU, vitamin C 452 IU, zinc 69.6 mg, lutein 8 mg, taurine 400 mg, omega-3 fatty acids 300 mg in combination with a micro-current stimulation device or a sham micro-current stimulation device (randomised).

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nutritional supplement

Primary outcome measure
Measure the change in visual acuity from baseline at six months.

Secondary outcome measures
Measure objective signs of improved macular function.

Overall study start date
01/04/2004

Completion date
05/04/2005

Eligibility

Key inclusion criteria
1. Signed written consent
2. Between the ages of 50 and 90, inclusive
3. Any race or gender
4. Diagnosis of nonexudative (dry) Age-related Macular Degeneration (AMD) in at least one eye having more than ten large soft drusen 63 um in diameter, within 3,000 um of the fovea centre, documented on macular exam, retinal angiography and fundus photographs
5. Able to understand and comply with the requirements of the trial
6. Best Corrected Visual Acuity (BCVA) in the trial eye(s) of 20/32 to 20/125 inclusive as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) (logMAR)
7. Subjects must not have conditions that limit the view to the fundus (e.g. vitreous haemorrhage, cataracts, an epiretinal membrane). All subjects with more than or equal to 2+ nuclear opacities and/or significant central opacity (Posterior SubCapsular opacity [PSC] or Anterior SubCapsular opacity [ASC]) more than 1+ will undergo Potential Acuity Meter (PAM) testing. If the vision is more than or equal to two lines improved on PAM over standard acuity measurement then the subject will not be eligible for the trial
8. Subjects must be available for a minimum trial duration of approximately six months
9. Subjects must agree to take only the nutritional supplement that is provided during this study
10. Subjects or eyes must not meet any of the exclusion criteria

Participant type(s)
Patient

Age group
Senior

Sex

Not Specified

Target number of participants
80

Key exclusion criteria
Any of the following excluded a subject from the trial:
1. Currently enrolled in an ophthalmic clinical trial
2. Eyes with concomitant macular or choroidal disorders other than AMD and with indefinite signs of AMD
3. Eyes with a diagnosis of exudative (wet) AMD with active SubRetinal NeoVascularisation (SRNV) or Choroidal NeoVascularisation (CNV) lesions requiring laser photocoagulation in the study eye
4. Subjects with significant ocular lens opacities causing vision decrease
5. Subjects with amblyopia
6. Subjects with optic nerve disease (neuropathy, atrophy, papilledema), unstable glaucoma as defined by intraocular pressures greater than 25 mmHg, three or more glaucoma medications, C /D of 0.8 or greater and visual fields consistent with glaucoma; history of retina-vitreous surgery, degenerative myopia, active posterior intraocular inflammatory disease, chronic use of topical ocular steroid medications, vasoproliferative retinopathies (other than AMD), rhegmatogenous retinal detachment, and inherited macular dystrophies
7. Subjects with demand type pacemakers or epilepsy
8. Subjects with uncontrolled hypertension (defined as diastolic of 90 or greater and systolic of 150 or greater)
9. Subjects with recent history (within the previous year) of cerebral vascular disease manifested with Transient Ischaemic Attacks (TIAs) or cerebral vascular accidents (CVAs)
10. Subjects with a history of Acquired Immune Deficiency Syndrome (AIDS)
11. Subjects who have received any previous experimental procedure in either eye or the use of any investigational drug or treatment within 30 days prior to enrolling in the trial
12. Subjects who have had intraocular surgery in trial eye within three months prior to enrolling in the trial
13. Smokers or any tobacco use

Date of first enrolment
01/04/2004

Date of final enrolment
05/04/2005

Locations

Countries of recruitment
United States of America

Study participating centre
119 Prospect Street
Ridgewood, NJ
United States of America
7450

Sponsor information

Organisation
Atlantic Medical, Inc. (USA)

Sponsor details
1213 Culbreth Drive
Wilmington, NC
United States of America
28405

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Atlantic Medical, Inc. (USA)

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?
Results article	results	26/02/2007		Yes	No