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MD Research News

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Drug treatment

Am J Ophthalmol. 2011 Jul 25. [Epub ahead of print]

Cataract Surgery in Ranibizumab-Treated Patients With Neovascular Age-Related Macular Degeneration From the Phase 3 ANCHOR and MARINA Trials.

Rosenfeld PJ, Shapiro H, Ehrlich JS, Wong P; Marina and Anchor Study Groups.

Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, Florida.

PURPOSE: To investigate whether cataract surgery was beneficial in patients with neovascular age-related macular degeneration (AMD) receiving monthly ranibizumab injections in the ANCHOR (Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD) and MARINA (Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD) phase 3 trials.

DESIGN: Retrospective analysis.

METHODS: Patients were identified who underwent cataract surgery during the 2 pivotal trials. For this analysis, the best-corrected visual acuity (VA) just prior to cataract surgery was referred to as the redefined baseline VA. For the period after cataract surgery, endpoints included change in VA, time to first postsurgery injection, and total number of injections. Monthly follow-up visits after surgery were defined at 30-day intervals ± 15 days.

RESULTS: Three subgroups were identified: study eyes of ranibizumab-treated patients (758 eyes [23 undergoing surgery]), fellow eyes of ranibizumab-treated patients (758 eyes [28 undergoing surgery]), and eyes of non-ranibizumab patients (762 [16 undergoing surgery]). Three months postsurgery, the VA of ranibizumab-treated eyes improved by a mean of 10.4 (± 3.4) letters compared to the redefined baseline (n = 20; 95% confidence interval +3.3 letters to +17.5 letters). The mean VA change from redefined baseline VA was not significantly different between the 3 groups at any of the evaluated time points postsurgery (P > .44 for all comparisons between each pair of the 3 groups at 1, 2, 3, and 4 months following surgery).

CONCLUSIONS: In the phase 3 trials, cataract surgery appeared to be safe and beneficial for all eyes with AMD, including ranibizumab-treated eyes with neovascular AMD. An average VA improvement of more than 2 lines was typically observed.

PMID: 21794843 [PubMed - as supplied by publisher]

Br J Ophthalmol. 2011 Jul 26. [Epub ahead of print]

Bevacizumab and ranibizumab tachyphylaxis in the treatment of choroidal neovascularisation.

Gasperini JL, Fawzi AA, Khondkaryan A, Lam L, Chong LP, Eliott D, Walsh AC, Hwang J, Sadda SR.

Torrance, California, USA.

Aims: To evaluate the effect of switching to bevacizumab or ranibizumab after developing tachyphylaxis during anti-vascular endothelial growth factor (VEGF) therapy for choroidal neovascularisation (CNV).

Methods: The authors reviewed the records of all patients who received both ranibizumab and bevacizumab for treatment of CNV to identify those who developed tachyphylaxis, defined as optical coherence tomography evidence of initial decreased exudation followed by lack of further reduction or an increase in exudation. Signs of exudation included subretinal fluid (SRF), pigment epithelial detachment (PED) and/or cystoid macular oedema (CMO).

Results: 26 eyes were included. 10 were initially treated with bevacizumab and then changed to ranibizumab for persistent SRF, PED and/or CMO. Of these, seven had occult CNV and three had predominantly classic CNV. One eye in the occult CNV group did not respond after being switched to ranibizumab. Six eyes had a positive therapeutic response, after one injection in four eyes, and after two or three injections in one eye each. In the classic group, two responded to ranibizumab and one did not. Sixteen eyes were initially treated with ranibizumab before changing to bevacizumab. Of these, 15 had occult CNV and 1 was predominantly classic. Three of the 16 eyes failed to respond to bevacizumab; 6 improved after one injection and 5 after two injections.

Conclusions: Patients with CNV who develop tachyphylaxis to ranibizumab or bevacizumab may respond to another anti-VEGF drug. The majority of cases (81%) in this series demonstrated at least some response after switching therapies.

PMID: 21791509 [PubMed - as supplied by publisher]

Other treatment & diagnosis

Invest Ophthalmol Vis Sci. 2011 Jul 26. [Epub ahead of print]

Quality and Reproducibility of Retinal Thickness Measurements in Two Spectral Domain Optical Coherence Tomography Machines.

Krebs I, Smretschnig E, Moussa S, Brannath W, Womastek I, Binder S.

The Ludwig Boltzmann Institute for Retinology and Biomicroscopic Laser Surgery, Vienna, Austria and.

Purpose: To evaluate the accuracy and reproducibility of retinal thickness measurements in exudative age-related macular degeneration (AMD) using the Spectralis and the Cirrus optical coherence tomography (OCT) machines.

Methods: Eyes with exudative age-related macular degeneration were randomly assigned to one of 8 groups each different concerning the sequence of examiner and the OCT device. The 512×128 cube program of Cirrus OCT and the Spectralis OCT volume scan 30×25° containing 32 lines were performed twice, respectively. The correlation between the examinations was expressed by the interclass correlation coefficient (ICC).

Results: 112 patients/eyes were enrolled aged mean 76.5±7.9 (51-89) years, 14 patients in each group, respectively. The mean error scores per line were 0.53 and 0.52 in Cirrus OCT, significantly ($p<0.001$) lower than in Spectralis OCT (0.83 and 0.98). For automatic CRT the ICC for Cirrus OCT (all examinations calculated) was 0.61 for group 1-4 (the same examiner) and 0.65 for group 5-8 (2 different examiners), for

Spectralis OCT (13.4% not calculated) the ICC was 0.93 for group1-4 and 0.86 for group 5-8. After error correction the ICC improved to 1.0 and 0.99 in Cirrus OCT and to 1.0 in both groups in Spectralis OCT.

Conclusion: Considerable differences between these two machines representing spectral domain technology were found. Different positioning of segmentation lines, control of localization, density of included scan lines, and number of available maps explain differences in segmentation quality and reproducibility. Manual correction of segmentation and centralization improves the reproducibility.

PMID: 21791591 [PubMed - as supplied by publisher]

Ophthalmologe. 2011 Jul;108(7):687-96.

[Electronic patient records and teleophthalmology : Part 2: concrete projects in ophthalmology].

[Article in German]

Schargus M, Michelson G, Grehn F.

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Abstract

Electronic storage of patient-related data will replace paper-based patient records in the near future. Because of the high visualization needed in ophthalmology integrated electronic data storage and usage will be very useful. Chronic diseases like glaucoma, macular degeneration and diabetic retinopathy would benefit from long-term data storage and analysis. Unfortunately there are nearly no widely accepted systems available providing these options. Another important point is the simplification of existing diagnostic procedures and nomenclature on an international level. Increasing mobility of patients requires a better portability of existing medical examination data between different physicians. This is the only way to provide continuously high levels of quality in patient care and to simultaneously reduce costs and prevent unnecessary secondary examinations.

PMID: 21796511 [PubMed - in process]

Ophthalmic Surg Lasers Imaging. 2011 Jul 1;42(4):S56-66. doi: 10.3928/15428877-20110627-05.

The Role of Spectral-Domain OCT in the Diagnosis and Management of Neovascular Age-Related Macular Degeneration.

Regatieri CV, Branchini L, Duker JS.

Abstract

Spectral-domain optical coherence tomography (SD-OCT) has emerged as the ancillary examination of choice to assist the diagnosis and management of neovascular age-related macular degeneration (AMD). SD-OCT provides more detailed images of intraretinal, subretinal, and subretinal pigment epithelium fluid when compared to time-domain technology, leading to higher and earlier detection rates of neovascular AMD activity. Improvements in image analysis and acquisition speed make it important for decision-making in the diagnosis and treatment of this disease. However, this new technology needs to be validated for its role in the improvement of visual outcomes in the context of anti-angiogenic therapy.

PMID: 21790112 [PubMed - in process]

Can J Ophthalmol. 2011 Jun;46(3):232-6. Epub 2011 May 27.

Visual function analysis in acute posterior vitreous detachment.

Schweitzer KD, Eneh AA, Hurst J, Bona MD, Rahim KJ, Sharma S.

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OBJECTIVE: To determine whether the visual function of patients with posterior vitreous detachment (PVD) changes between the initial visit and a 6-week follow-up visit, and to compare their visual function with that of patients with macular degeneration, cataract, glaucoma, low vision, cytomegalovirus (CMV) retinitis, or diabetic retinopathy and a reference population.

DESIGN: Prospective cohort study.

PARTICIPANTS: All patients presenting to the Hotel Dieu Hospital Emergency Eye Clinic between September 2008 and June 2009 who were diagnosed with acute PVD were offered enrollment in the study.

METHODS: Patients were administered the National Eye Institute Visual Function Questionnaire NEI VFQ-25 at two points in time. The composite scores from the initial and the 6-week visits were compared. The scores were also compared with established normative data and 6 ophthalmologic diagnoses.

RESULTS: The NEI VFQ-25 composite score for patients with acute PVD (n = 84) at baseline was 93.26 ± 5.59 (mean ± SD). After 6 weeks and a second ocular examination, there was no statistical difference in the composite score of 93.47 ± 6.20 (mean ± SD). (1-sided paired t-test, t = 0.57; P = 0.28).

CONCLUSIONS: The visual function of patients with acute PVD remains stable over the first 6 weeks after diagnosis. It is significantly higher than that of patients with 6 other ophthalmologic conditions but comparable to that of a normal population.

PMID: 21784207 [PubMed - in process]

Epidemiology & pathogenesis

Clin J Am Soc Nephrol. 2011 Jul 22. [Epub ahead of print]

Vision-Threatening Retinal Abnormalities in Chronic Kidney Disease Stages 3 to 5.

Deva R, Alias MA, Colville D, Tow FK, Ooi QL, Chew S, Mohamad N, Hutchinson A, Koukouras I, Power DA, Savige J.

Northern Health, Melbourne, Victoria, Australia

Summary Background and objectives: Retinal abnormalities are common in inherited and acquired renal disease. This study determined their prevalence in chronic kidney disease (CKD) stages 3 to 5.

Design, setting, participants, & measurements: One hundred fifty patients with CKD stages 3 to 5 and 150 age- and gender-matched hospital patients with CKD stages 1 to 2 underwent bilateral retinal photography. These images were reviewed for incidental abnormalities, microvascular (Wong and Mitchell classification) and diabetic retinopathy (Airlie House criteria), and macular degeneration (Seddon classification).

Results: Three (2%) patients with CKD stages 3 to 5 had retinal features characteristic of inherited renal disease (atrophy in Myopathy, Encephalopathy, Lactic Acidosis, Stroke-like episodes [MELAS] syndrome; and 2 with drusen in dense deposit disease). Fifty-nine (39%) patients had moderate-severe microvascular retinopathy (hemorrhage, exudates) compared with 19 (13%) with CKD stages 1 to 2. Forty-one (28%) had moderate-severe diabetic retinopathy (microaneurysms, exudates) compared with 16 (11%) with CKD stages 1 to 2. Ten (7%) had severe macular degeneration (geographic atrophy, hemorrhage, exudates,

membranes) compared with one (1%) with CKD stages 1 to 2. Renal failure was an independent risk factor for microvascular retinopathy, diabetic retinopathy, and macular degeneration. Eleven (7.3%) patients with renal failure and one (0.7%) with CKD stages 1 to 2 had previously unrecognized vision-threatening retinal abnormalities that required immediate ophthalmologic review.

Conclusions: Retinal abnormalities are common in CKD stages 3 to 5, and are more severe and more likely to threaten vision than in hospital patients with CKD stages 1 to 2.

PMID: 21784818 [PubMed - as supplied by publisher]

Eur J Ophthalmol. 2011 Jul 13. pii: FF1678A6-1CA9-4722-9712-2F3FCF670073. doi: 10.5301/ejo.5000023. [Epub ahead of print]

Patients with neovascular age-related macular degeneration in Spain display a high cardiovascular risk.

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Purpose: Cardiovascular disease and its risk factors may have a significant role in the development of neovascular age-related macular degeneration (NV-AMD). This study aims to assess the impact of these factors in this population and define their level of cardiovascular risk according to the Framingham model.

Methods: This was a cross-sectional, observational, multicenter study that included patients aged 50 years or older who attended ophthalmic centers for the diagnosis or follow-up of NV-AMD. Information collected included demographic and AMD data, a complete history of cardiovascular disease and its risk factors, lipid profile, blood pressure, and treatment history.

Results: The study population consisted of 901 patients, predominantly Caucasian, with a mean age of 75.7 years, receiving anti-vascular endothelial growth factor therapy for their NV-AMD in 77.7% of the cases. Blood pressure measurement during the study visit and lipid analyses revealed poor control in 67.7% and 93.3% of the patients, respectively. Hypertension was the most prevalent cardiovascular risk factor (77.7%), followed by a history of cardiac disease or other forms of atherosclerotic disease (53.8%). Diabetes was present in 28% of the subjects. The study population was considered a high-risk population according to the National Cholesterol Education Program Expert Panel Clinical Guidelines (NCEP ATP III), with a probability of a cardiovascular event in 10 years of 19.3% according to the Framingham model.

Conclusions: This NV-AMD population is associated with a significant cardiovascular risk, and the Framingham model can help us identify those subjects with higher risk levels in order to improve their overall management.

PMID: 21786274 [PubMed - as supplied by publisher]

J Biol Chem. 2011 Jul 24. [Epub ahead of print]

PBN ({alpha}-phenyl-N-tert-butyl nitrone) Prevents Light-induced Degeneration of the Retina by Inhibiting RPE65 Isomerohydrolase Activity.

Mandal MN, Moiseyev GP, Elliott MH, Kasus-Jacobi A, Li X, Chen H, Zheng L, Nikolaeva O, Floyd RA, Ma JX, Anderson RE.

OUHSC, United States;

Abstract

PBN (α-phenyl-N-tert-butyl nitrone), a free radical spin trap, has been shown previously to protect retinas

against light-induced neurodegeneration but the mechanism of protection is not known. Here we report that PBN-mediated retinal protection likely occurs by slowing down the rate of rhodopsin regeneration by inhibiting RPE65 activity. PBN (50 mg/kg) protected albino Sprague-Dawley (SD) rat retinas when injected at 0.5 to 12 h before exposure to damaging light at 2,700 lux intensity for 6 h, but had no effect when administered after the exposure. PBN injection significantly inhibited in vivo recovery of rod photoresponses and the rate of recovery of functional rhodopsin photopigment. Assays for visual cycle enzyme activities indicated that PBN inhibited one of the key enzymes of the visual cycle, RPE65, with an IC50 = 0.1 mM. The inhibition type for RPE65 was found to be uncompetitive with Ki = 53 μM. PBN had no effect on the activity of other visual cycle enzymes, lecithin retinol acyltransferase (LRAT) or retinol dehydrogenases (RDHs). Interestingly, a more soluble form of PBN, N-tert-butyl-α-(2-sulfophenyl) nitrone (S-PBN), which has similar free radical trapping activity did not protect the retina or inhibit RPE65 activity, providing some insight into the mechanism of PBN specificity and action. Slowing down the visual cycle is considered a treatment strategy for retinal diseases such as Stargardt and dry age-related macular degeneration (AMD) in which toxic byproducts of the visual cycle accumulate in retinal cells. Thus, PBN inhibition of RPE65 catalytic action may provide therapeutic benefit for such retinal diseases.

PMID: 21785167 [PubMed - as supplied by publisher]

Am J Ophthalmol. 2011 Aug;152(2):153-4.

Race/Ethnicity and age-related macular degeneration.

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Department of Ophthalmology and Visual Sciences, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin.

PMID: 21784191 [PubMed - in process]

Genetics

Genome Med. 2011 Jul 28;3(7):51. [Epub ahead of print]

Predictive genetic testing for the identification of high-risk groups: a simulation study on the impact of predictive ability.

Mihaescu R, Moonesinghe R, Khoury MJ, Janssens AC.

BACKGROUND: Genetic risk models could potentially be useful in identifying high-risk groups for the prevention of complex diseases. We investigated the performance of this risk stratification strategy by examining epidemiological parameters that impact the predictive ability of risk models.

METHODS: We assessed sensitivity, specificity, positive and negative predictive value for all possible risk thresholds that can define high-risk groups and investigated how these measures depend on the frequency of disease in the population, the frequency of the high-risk group, and the discriminative accuracy of the risk model, as assessed by the area under the receiver-operating characteristic curve (AUC). In a simulation study, we modeled genetic risk scores of 50 genes with equal odds ratios and genotype frequencies, and varied the odds ratios and the disease frequency across scenarios. We also performed a simulation of age-related macular degeneration risk prediction based on published odds ratios and frequencies for six genetic risk variants.

RESULTS: We show that when the frequency of the high-risk group was lower than the disease frequency, positive predictive value increased with the AUC but sensitivity remained low. When the frequency of the high-risk group was higher than the disease frequency, sensitivity was high but positive predictive value

remained low. When both frequencies were equal, both positive predictive value and sensitivity increased with increasing AUC, but higher AUC was needed to maximize both measures.

CONCLUSIONS: The performance of risk stratification is strongly determined by the frequency of the high-risk group relative to the frequency of disease in the population. The identification of high-risk groups with appreciable combinations of sensitivity and positive predictive value requires higher AUC.

PMID: 21797996 [PubMed - as supplied by publisher]

DNA Cell Biol. 2011 Jul 26. [Epub ahead of print]

Age-Related Macular Degeneration and Association of CFH Y402H and LOC387715 A69S Polymorphisms in a Turkish Population.

Soysal Y, Inan UU, Küsbeci T, Imirzalioğlu N.

1 Afyon Kocatepe University , Faculty of Medicine, Department of Medical Genetics, Ali Çetinkaya Kampusu, Dekanlik Binasi, Afyonkarahisar, Turkey .

Abstract

Age-related macular degeneration (AMD) is a disease with multifactorial etiology characterized by irreversible loss of central visual acuity. The discovery of susceptive single-nucleotide polymorphisms (SNPs) has progressed our understanding of AMD. Complement factor H (CFH) gene Y402H polymorphism and high-temperature requirement A-1 (HTRA1) LOC387715 gene A69S polymorphisms are the most important SNPs reported in the literature. Determination of genetic risk factors and genotype-phenotype relationship in AMD may result in rapid and cost-effective therapeutic applications for young and old population. In this study, we hypothesized a potential association between CFH gene Y402H and HTRA1 LOC387715 gene A69S polymorphism in Turkish AMD patients. In blood samples from a total of 252 individuals, 147 clinically diagnosed as AMD and the others control, polymorphic sites in CFH, Y402H (Tsp509I T/C), and HTRA1, LOC387715 A69S (FnuHI G/T), were determined by polymerase chain reaction-restriction fragment length polymorphism analysis. There was significant difference between CFH genotypes in the AMD group, TT 21.8%, TC 48.3%, and CC 29.9%, and in the control subjects, TT 45% (p=0.003), TC 41% (p=0.0001), and CC 14% (p=0.0001). Further, the A69S polymorphism of LOC387715 was investigated and found to be significantly associated with AMD. LOC387715 genotypes in the AMD group were GG 30.6%, GT 38.1%, and TT 31.3% and in the control subjects were GG 59% (p=0.027), GT 39% (p=0.0001), and TT 2% (p=0.0001), respectively. We also found that Y402H C and A69S T allele were associated with AMD. This is the first study showing that Y402H and LOC387715 are associated with AMD in Turkish population.

PMID: 21790300 [PubMed - as supplied by publisher]

Eur J Ophthalmol. 2011 Jul 14. pii: 0F78248D-02C2-4C49-AD31-0B59157F53F1. doi: 10.5301/ejo.5000029. [Epub ahead of print]

Bilateral choroidal neovascularization associated with bilateral ABCA4 gene mutation.

Battaglia Parodi M, De Benedetto U, Knutsson KA, Bandello FM.

Department of Ophthalmology, University Vita-Salute, San Raffaele Scientific Institute, Milan - Italy.

Purpose: To describe a case of ABCA4 gene mutation (G1961E) associated with bilateral choroidal neovascularization (CNV) treated with intravitreal ranibizumab injections.

Methods: A 52-year-old man with bilateral CNV associated with ABCA4 gene mutation underwent complete ophthalmologic examination over a 30-month follow-up and was treated with intravitreal ranibizumab injec-

tions on an as-needed basis.

Results: Baseline best-corrected visual acuity (BCVA) was 20/32 in the right eye (RE) and 20/63 in the left eye (LE). Two small CNVs with juxtafoveal location were detectable in the RE, whereas a single subfoveal CNV was visible in the LE. Overall, 6 and 9 intravitreal ranibizumab injections were administered in RE and LE, respectively, during the 30-month follow-up. At the end of the follow-up, BCVA was 20/100 in the RE and 20/200 in the LE.

Conclusions: This case report reveals that ABCA4 gene mutation may be complicated by multiple and bilateral CNVs. Intravitreal injection of ranibizumab can achieve temporary CNV stabilization, but cannot guarantee complete quiescence over a long-term follow-up. Other therapeutic approaches could be necessary to accomplish visual acuity preservation.

PMID: 21786275 [PubMed - as supplied by publisher]

Am J Ophthalmol. 2011 Aug;152(2):325-6.

Polymorphisms in ARMS2 (LOC387715) and LOXL1 Genes in the Japanese With Age-Related Macular Degeneration.

Lepre T, Cascella R, Missiroli F, De Felici C, Taglia F, Zampatti S, Cusumano A, Ricci F, Giardina E, Eandi CM, Novelli G.

Rome, Italy.

PMID: 21784201 [PubMed - in process]

Pre-clinical

J Biomater Sci Polym Ed. 2011 Jul 21. [Epub ahead of print]

Mouse Retinal Progenitor Cell Dynamics on Electrospun Poly(ε-Caprolactone).

Cai S, Smith ME, Redenti SM, Wnek GE, Young MJ.

Abstract

Age-related macular degeneration, retinitis pigmentosa and glaucoma are among the many retinal degenerative diseases where retinal cell death leads to irreversible vision loss and blindness. Working toward a cell-replacement-based therapy for such diseases, a number of research groups have recently evaluated the feasibility of using retinal progenitor cells (RPCs) cultured and transplanted on biodegradable polymer substrates to replace damaged retinal tissue. Appropriate polymer substrate design is essential to providing a three-dimensional environment that can facilitate cell adhesion, proliferation and post-transplantation migration into the host environment. In this study, we have designed and fabricated a novel, ultra-thin electrospun poly(ε-caprolactone) (PCL) scaffold with microscale fiber diameters, appropriate porosity for infiltration by RPCs, and biologically compatible mechanical characteristics. We have verified that our electrospun PCL scaffold supports robust mouse RPC proliferation, adhesion, and differentiation in vitro, as well as migration into mouse retinal explants. These promising results make PCL a strong candidate for further development as a cell transplantation substrate in retinal regenerative research.

PMID: 21781383 [PubMed - as supplied by publisher]

Diet

Clinics (Sao Paulo). 2011;66(5):743-6.

The role of oxidative stress and antioxidants in the pathogenesis of age-related macular degeneration.

Yildirim Z, Ucgun NI, Yildirim F.

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OBJECTIVE: To investigate the role of oxidant/antioxidant status and protein oxidation in the development of age-related macular degeneration.

METHOD: The activities of serum superoxide dismutase and glutathione peroxidase and the levels of serum malondialdehyde, advanced oxidation protein products, glutathione and vitamin C were measured in 25 patients with age-related macular degeneration and 25 control subjects without age-related macular degeneration.

RESULT: The malondialdehyde and advanced oxidation protein product levels in the serum were significantly higher in the age-related macular degeneration patient group than in the control group ($p<0.05$). The superoxide dismutase activity in the serum was significantly lower in the age-related macular degeneration patient group than in the control group ($p<0.05$). The levels of vitamin C and glutathione and the activity of glutathione peroxidase in the serum were unchanged between groups ($p>0.05$).

CONCLUSION: The results of the present study suggest that decreased effectiveness of the antioxidant defense system and increased oxidative stress may play a role in the pathogenesis of age-related macular degeneration.

PMID: 21789374 [PubMed - in process] PMCID: PMC3109369