Design implications and study categories

AREDS (Age-related Eye Disease Study) was a prospective, multicentric, randomised clinical trial conducted between 1992 and 2006, mainly sponsored by the National Eye Institute (NEI) of the National Institutes of Health (NIH).

This study was designed to evaluate the clinical aspects, natural course and risk factors associated with age-related cataract and AMD, as well as the effects of antioxidant vitamins and minerals on these two ocular conditions.

Eligible patients were aged 55-80 by occasion of enrolment and required to be free of any illness or condition that would make long-term follow-up or compliance with study medications unlikely or difficult.

Participants were placed in one of several **AMD categories** according to fundus photographs graded by a central reading centre, best corrected visual acuity and ophthalmic examination[(10)]:

AREDS category 1 – (No AMD) – this was the AREDS control group, consisting of patients with no or a few small drusen (<63 microns in diameter).

AREDS category 2 – (Early AMD) – characterised by a combination of multiple small drusen, a few intermediate drusen (63 to 124 microns in diameter) or RPE abnormalities.

AREDS category 3 – (Intermediate AMD) – characterised by extensive intermediate drusen, at least one large drusen (>125 microns in diameter) or geographic atrophy not involving the centre of the fovea.

AREDS category 4 – (Advanced/Late AMD) – characterised by one or more of the following (in the absence of other causes), in one eye:

Geographic atrophy of the RPE and choriocapillaris, including the centre of the fovea

Neovascular maculopathies, such as the following: Choroidal neovascularization (CNV)

Serous and/or haemorrhagic detachment of the sensory retina or the RPE

Hard exudates in the retina

Subretinal and sub-RPE fibrovascular proliferation

Disciform scar[(10)].

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