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A Clinical Trial to evaluate an anti-angiogenic drug in the treatment of AMD

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Introduction: There is currently no standard effective therapy for most patients with Age Related Macular Degeneration (AMD). The treatments more often used recently are thermal laser photocoagulation and photodynamic therapy. However, less than 50% of these patients with the neovascular form of AMD are amenable to these forms of therapy, and high rates of recurrence are common.. There are many investigational treatments, but none have yet been demonstrated to be effective. Purpose: To describe a study designed in the Federal University of São Paulo (UNIFESP-EPM) to determine the role of an anti-angiogenic drug in exudative AMD, in inhibiting neovascular leakage and angiogenesis. Methods: This study is a phase II/III, randomized, double-masked, controlled, dose ranging, multicenter comparative trial. The objective is to establish the safety and efficacy of intravitreal injections of anti-VEGF (Vascular Endothelium Growth Factor) aptamer given every 6 weeks for 54 weeks. The inclusion criteria are subfoveal choroidal neovascularization (CNV) secondary to AMD with a total lesion size < 12 disc areas. Best corrected visual acuity in the study eye must be between 20/40 and 20/320 and better or equal to 20/800 in the fellow eye. Visual acuity is the main outcome measure. Discussion: VEGF is a key mediator in the initial stages of the neovascular form of AMD. It is argued that its inhibition could have some impact on the onset and/or severity of the visual loss associated with vascular growth and subsequent subretinal hemorrhage, which is characteristic of the disease. Conclusion: A randomized, multicenter, controlled clinical trial is essential to gain definitive information about the utility of this approach in patients with subretinal neovascular membranes in AMD.