

The MIVI III (Microplasmin for Vitreous Injection III) Trial

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Advantages:

Previous clinical evaluation has shown microplasmin to be generally well tolerated and able to induce PVD as well as nonsurgical traction release and in some cases nonsurgical macular hole closure.

Methods:

The purpose of this trial is to evaluate the safety and efficacy of several doses of intravitreal microplasmin in comparison to placebo when administered 7 days prior to pars plana vitrectomy to facilitate the creation of a posterior vitreous detachment (PVD). This is a multicenter, randomized, placebo-controlled, double-masked, parallel-group, dose-ranging clinical trial, with approximately 120 patients randomized to 1 of the following (all administered 7 days [\pm 1 day] prior to 20, 23, or 25 gauge pars plana vitrectomy): Placebo, 25 μ g, 75 μ g, or 125 μ g intravitreal microplasmin injection. Patients with nonproliferative vitreoretinal disease without evidence of a posterior vitreous detachment (PVD) over the macula in whom vitrectomy is indicated were eligible for the trial.

Effectiveness / Safety:

Enrolment has been completed with 125 patients treated in the trial. Unmasked safety and efficacy results for all patients up to and including the 35 day follow-up visit will be presented. Results from the MIVI III trial provide an opportunity to corroborate encouraging results from prior trials and to further delineate the dose response relationship for this exciting molecule.