

Use of Immune Globulin Intravenous (Human) To Treat Age-Related Macular Degeneration

Title of the study:	Multicenter, randomized, double-blind, placebo-controlled, study to evaluate the efficacy and safety of IGIV-Chromatography (IGIV-C), 10% treatment in subjects with pure occult choroidal neovascularization due to age related macular degeneration.
Publications (references):	This study has not been published yet in a peer-reviewed journal
Clinical phase:	2
Number of patients:	<p>Enrolled (screened): 96</p> <p>Randomized: 57 (30 allocated to the IGIV-C group, 27 allocated to the placebo group)</p> <p>Completed: 38 (22 of the IGIV-C group, 16 of the placebo group)</p> <p>With the exception of 4 subjects (1 of the IGIV-C group and 3 of the placebo group), all randomized subjects were valid for the Intent-to-Treat (ITT) analysis (primary analysis population).</p> <p>All subjects were Caucasians and more than two thirds (70%) were women. Their mean age was 74.4 ± 9.2 years and ranged between 52 and 92 years.</p>
Test product, dose and mode of administration:	<p>Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified (IGIV-C, Gamunex[®], TAL-05-00004, previously BAY 41-1000).</p> <p>The dose per infusion cycle was 2 g/kg body weight (bw) over 5 consecutive days (= 4 mL/kg bw/infusion).</p>
Reference therapy, dose and mode of administration:	<p>Placebo consisted of a 20% or 25% albumin concentrate diluted with glucose 5% to a final concentration of 0.1% albumin as an intravenous infusion.</p> <p>The dose per infusion cycle was 0.1% albumin over 5 consecutive days (= 4 mL/kg bw/infusion).</p>
Criteria of evaluation:	<p>Efficacy:</p> <p>The primary efficacy variable was the change in the logarithm of the minimal angle of resolution (LogMAR) from baseline to endpoint (defined as LogMAR assessment at Week 12 or last LogMAR assessment at or later than Week 8 during the 3-month treatment period; end of treatment (EOT)).</p> <p>Safety:</p> <ul style="list-style-type: none"> • Adverse events (AEs) • Vital signs • Laboratory data outside the normal range

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<p>Statistical methods: The primary efficacy comparison for the change in LogMAR in the study eye from baseline to endpoint was a two-way ANOVA with treatment group and center as fixed factors (main effect model).</p>
<p>Summary of efficacy: The mean changes of the LogMAR from baseline to the EOT (primary efficacy variable) were not statistically significant between the two treatment groups. Comparison of the changes of LogMAR by ANOVA (main effect model) resulted in a treatment difference (IGIV-C minus placebo) of 0.04 (95% CI: -0.07 to 0.15), which was neither clinically nor statistically significant ($P = 0.49$). The supportive analysis, which additionally included the baseline LogMAR value as covariate (ANCOVA, saturated model) produced similar results as that of the primary analysis.</p>
<p>Summary of safety: With the exception of serious adverse events (SAEs), which occurred more frequently in the placebo group (18.5%) than in the IGIV-C group (3.3%), the incidence rates of other adverse event types were nearly identical in the two treatment groups. Drug-related, treatment emergent adverse events (TEAEs) that occurred in at least 2 subjects of either treatment group were: 'fatigue' (2 subjects of the IGIV-C group, none in the placebo group), 'blood pressure increased' (3 subjects of the placebo group, 1 in the IGIV-C group), and 'pruritus' (2 subjects in the placebo group, none in the IGIV-C group). None of the drug-related TEAEs was severe or serious, and most of these events improved or resolved by the end of the study.</p> <p>Standard parameters of hematology and serum chemistry were in general not affected by the infusions, neither during the treatment period nor during the 3-months follow-up. The levels of immune globulins, total protein, albumin, and plasma viscosity were increased in all subjects of the IGIV-C group after each infusion cycle. No adverse events were associated with these transient increases.</p>