End of Study Report - LIMO Study
Eudract 2011-001869-41
An exploratory study of Ranibizumab (Lucentis) for treatment of Uveitic Patients with Refractory Cystoid Macular Oedema
(The LIMO Study)

The study achieved its objectives as summarized in the abstract below. The findings will shortly be submitted for publication and fed back to the participants.

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Purpose The objective of this study was to investigate the efficacy and safety of intravitreal Ranibizumab (Lucentis) in improving visual outcome for patients with uveitis and quiet (non-inflamed) eyes with visual loss secondary to cystoid macular oedema (CMO), which has proven refractory or ineligible to standard treatment.

Design Open label, prospective non-randomised interventional case series.

Methods Single centre study. Ten eyes of 10 patients with quiescent uveitis and CMO ineligible for, or refractory to, standard therapy were enrolled. Subjects received 3 initial monthly injections of ranibizumab in the study eye, and subsequent monthly retreatment based on clinical need. Follow up was 12 months. Patients underwent baseline and serial assessments including best-corrected visual acuity (BCVA), contrast sensitivity, reading speed, microperimetry, electrophysiology and optical coherence tomography (OCT). Primary endpoints of the study were the number of eyes which responded to therapy and change in central retinal thickness as measured by OCT at both 6 and 12 months.

Results Ten patients (5 male) were enrolled. Median age was 56.1 years (IQR 37.4, 68.2), median duration of macular oedema was 30 months (22, 45) and median BCVA in the study eye was 64 ETDRS letters (58, 68). One patient (10%) had anterior uveitis, six (60%) had intermediate uveitis, one (10%) had posterior uveitis, and two (20%) had panuveitis. The median number of intravitreal injections over the study period was 7.5 (5, 9.5). Nine patients (90%) responded to therapy albeit with a variable reduction in macular oedema. At 6 months and at 12 months median BCVA was 68 (53, 80) and 60 (42, 78) respectively. Three patients (30%) gained more than 15 letters and 3 patients (30%) gained more than 10 letters; 3 patients (30%) lost more than 15 letters and no patient lost more than 30 letters. Median CMT was 474 μm (407, 603) at baseline and decreased by 42.5 μm (-140, 4) and 5 μm (-183, 100) at 6 and 12 months respectively. There was no change in contrast sensitivity, but reading speed improved by a median 21.5 words per minute (-50, 36), and macular sensitivity on microperimetry improved by 7.5 dB (-0.2, 13.2). One patient (10%), with pre-existing mild cataracts developed significant cataract during the study. There were no serious adverse events.

Conclusions A variable response to intravitreal ranibizumab was observed in this small cohort of patients with chronic macular oedema and quiescent uveitis, but the majority of patients showed a response to treatment. Our pilot study suggests further investigation in a larger cohort would be worthy of consideration.