

## **ABSTRACT**

### **Background/aims**

To evaluate the clinical efficacy and safety of combined repeated Ozurdex and macular laser therapy (MLT) compared with MLT monotherapy in participants with visual impairment due to centre involving diabetic macular oedema (DMO).

### **Methods**

80 patients with best corrected visual acuity (BCVA) between 54 and 78 ETDRS letters due to centre involving DMO were randomised to combination therapy with Ozurdex and MLT or MLT only. The combination arm received mandated Ozurdex injections at baseline and 16 weeks followed by retreatment criteria-guided pro-re-nata therapy at 32 and 48 weeks. Patients randomised to MLT only were treated every 16 weeks if clinically significant macular oedema was present. The primary outcome was the mean change from baseline in BCVA between arms at 56 weeks.

### **Results**

The mean change in BCVA at 56 weeks was  $-0.3$  (SD 11.4) ETDRS letters in the combination arm versus  $+0.4$  (SD 9.6) ETDRS (Early Treatment Diabetic Retinopathy study) letters in the MLT arm (effect estimate 1.15 (95% CI  $-3.32$  to  $5.61$ )). However, at 56 weeks, a post hoc comparison of central subfield thickness (CST) showed a decrease of  $-113\mu\text{m}$  (IQR  $-218$ ,  $-64$ ) (combination) versus  $-17\mu\text{m}$  ( $-128$ ,  $12$ ) (MLT arm) ( $p < 0.001$ ). Elevated intraocular pressure requiring topical therapy was observed in 8 (20%) eyes in the combination versus 1 (2.5%) in the MLT arm. 33% (9/27) of phakic patients in the combination arm underwent cataract surgery.

### **Conclusions**

Visual outcome following combination therapy did not differ from MLT alone in the centre involving DMO despite a significant decrease in CST likely due to an entry visual acuity-related ceiling effect and cataract development.

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