

## **A slow-release dexamethasone preparation in proliferative vitreoretinopathy; a prospective randomised controlled clinical trial**

Authors: <sup>1,2</sup> Philip J Banerjee BMedSci FRCOphth, <sup>1,2</sup> Ana Qartilho \*\* <sup>1,2</sup>, Catey Bunce DSc, <sup>1,2</sup> Wen Xing MSc, <sup>1,2</sup> Tapiwa M Zvobgo, <sup>1,2</sup> Nicola Harris, <sup>1,2</sup> David G Charteris MD FRCS(Ed) FRCOphth

<sup>1</sup> Moorfields Eye Hospital, 162 City Road, London EC1V 2PD

<sup>2</sup> NIHR Clinical Research Facility at Moorfields Eye Hospital

### **Abstract**

**Purpose:** To test the hypothesis that adjunctive slow release dexamethasone implant (Ozurdex<sup>®</sup>) can improve the outcomes of vitreoretinal surgery for established (Grade C) proliferative vitreoretinopathy (PVR)

**Setting:** A three-year, single-centre prospective, participant and surgeon-masked randomized-controlled-clinical trial. Patients requiring vitrectomy surgery for retinal detachment (RD) with PVR were randomized to standard (control) or study treatment (adjunct).

**Methods:** Intraoperatively, the adjunct group received a 0.7mg slow-release dexamethasone implant (Ozurdex) at the time of vitrectomy surgery, repeated at silicone oil removal. The control group received standard care.

Primary outcome measure was stable retinal reattachment with removal of silicone oil without additional vitreoretinal surgical intervention at 6 months. Secondary outcomes included i) final visual acuity (median and ETDRS of 55 letters or better), ii) cystoid macula oedema (CMO), foveal thickness and macular volume iii) development of PVR recurrence, iv) complete and posterior retinal reattachment, vi) tractional RD, vii) hypotony/raised IOP, viii) macula pucker/epiretinal membrane, ix) cataract, x) quality of life

**Results:** All 140 patients were recruited within 25 months of study commencement; 138 patients had primary outcome data. Primary outcome assessment showed similar results in anatomical success between the groups (49.3% vs 46.3%, adjunct vs control, (Odds Ratio 0.89, 95% Confidence

interval 0.46 – 1.74,  $p= 0.733$ ). Mean visual acuity at 6 months was 38.3 ETDRS letters and 40.2 letters in the adjunct and control group, respectively. Secondary anatomical outcomes (complete/posterior reattachment rates and PVR recurrence) were comparable between groups. At 6 months, fewer adjunct patients had CMO (42.6%) or a foveal thickness of  $<300\mu\text{m}$  (42.8%) compared to controls (65.2% and 60.0%, respectively).

**Conclusion:** A slow-release dexamethasone implant does not improve the primary anatomical success rate in eyes undergoing vitrectomy surgery with silicone oil for PVR. Further clinical trials are indicated to improve anatomical and visual outcomes in these eyes.

**Financial Disclosure:** YES- the study was funded by an unrestricted research grant from Allergan, Ireland, which included the supply of the investigational medicinal product