FINAL STUDY REPORT

Study Title: A pilot study of intraocular use of intensive anti-inflammatory; Triamcinolone Acetonide to prevent proliferative vitreoretinopathy in eyes undergoing vitreoretinal surgery for open globe trauma; the adjuncts in ocular trauma (AOT) trial

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Purpose: The Adjuncts in Ocular Trauma (AOT) Trial investigated the effect of using intensive anti-inflammatory agents (intravitreal and subtenons Triamcinolone acetonide, oral flurbiprofen and guttae prednisolone acetate 1%) peri-operatively in patients undergoing pars plana vitrectomy surgery following Open Globe Trauma (OGT). This pilot study was conducted to provide outcome data to power a definitive randomized controlled clinical trial. It also aimed to assess the feasibility of conducting a trial of this nature in this patient population, particularly in terms of case availability and recruitment rates.

Setting: This was a pilot, single-centre prospective, participant and surgeon-masked randomized-controlled-clinical trial

Methods: Forty patients requiring vitrectomy surgery following OGT were randomized to either standard or study treatment in a 1:1 allocation ratio, with care differing only in the addition of supplementary adjunctive agents in the adjunct group.

Outcome Measures: Primary outcome measure was anatomical success at six months in the absence of internal tamponade. Secondary outcomes included final visual acuity, occurrence of PVR, IOP rise, number of operations and recruitment rate.

Results: All 40 patients were recruited within 22 months of study commencement; 39 patients had outcome data. Primary outcome assessment showed no difference in anatomical success between the two groups.

Anatomical success was 50 % (10/20) in the adjunct group, compared to 47% (9/19) in the standard group (Odds Ratio 1.11, 95% Confidence Interval 0.316 - 3.904). Visual outcomes showed a trend towards a positive treatment effect, with a final median visual acuity of 31 ETDRS letters in the adjunct group, compared to 25 ETDRS letters in the standard group. A higher proportion of patients gained 10, 20 and 30 ETDRS letters in the adjunct group (80%, 65% and 50%, respectively) compared to the standard group (52.6%, 52.6% and 42.1%). Fewer patients had poor visual outcomes (Zero ETDRS letters) in the adjunct group (15%, n=3) compared to the standard group (42.1%, n=8). Postoperative PVR incidence was higher in the standard group at all time-points. No difference in the number of operations to achieve anatomical success was observed.

A manuscript reporting the results of this trial is currently being drafted and will be submitted to peer –reviewed medical journals. The results will also be presented at national and international scientific meetings. The trials team are endeavouring to organise a patient feedback day in order to disseminate the results to those trial participants who are keen to attend.

Conclusion: This pilot study achieved its aims by confirming that an RCT in this population is deliverable and estimated recruitment rates are realistic. Intensive anti-inflammatory agents may be a useful adjunct in this disease group and an adequately powered randomised control trial is justified. The results of this pilot study have helped to secure an NIHR research grant via the HTA funding stream in order to conduct a multicentre RCT to definitively answer the question; i.e. whether per-operative intraocular and periocular triamcinolone given at the time of vitrectomy surgery following open globe trauma improves visual outcome.