End of Study Report; RaDiVit Study

Eudract 2010-024062-22; Protocol Number BAIJ1006

A randomized controlled trial of RAnibizumab pretreatment in DIabetic VITrectomy (the RaDiVit pilot study)

Trial registration: NCT01306981, registered March 1st 2011

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.

Principal Investigator

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Purpose

To determine the impact of adjunctive intravitreal ranibizumab on the outcome of vitrectomy surgery for proliferative diabetic retinopathy

Design

Pilot randomized controlled trial

Methods

This was a single center study including 30 eyes of 30 subjects having vitrectomy surgery for proliferative diabetic retinopathy with tractional retinal detachment. Subjects were randomized to receive either intravitreal ranibizumab injection or control (subconjunctival saline injection) 7 days prior to surgery. The primary outcome measure was best-corrected visual acuity at 12 weeks after surgery.

Results

Mean (SD) visual acuity at 12 weeks post-operatively was 52.6 (21) letters in the ranibizumab group and 46.7 (25) letters in the control group (Table 2). There was a mean improvement from baseline by 24 (27) letters in the ranibizumab group, and by 14 (31) letters in the control group. We measured no difference in progressive retinal detachment, duration of surgery or technical difficulty. Vitreous cavity hemorrhage persisted at 12 weeks in 2 subjects in the control arm and in none in the ranibizumab arm. Vitreous levels of vascular endothelial growth factor and interleukin 1α at the time of surgery were lower in the ranibizumab group.

Conclusions

Ranibizumab delivered one week prior to vitrectomy surgery for advanced proliferative diabetic retinopathy may result in improved visual acuity 12 weeks post-operatively. This difference may be the result of a lower incidence of vitreous cavity hemorrhage and warrants further exploration in a definitive randomized clinical trial.