Intravitreal aflibercept compared with panretinal photocoagulation for proliferative diabetic retinopathy: the CLARITY non-inferiority RCT

Sobha Sivaprasad,1,2* Philip Hykin,1 A Toby Prevost,3 Joana Vasconcelos,3 Amy Riddell,4 Jayashree Ramu,1 Caroline Murphy,4 Joanna Kelly,4 Rhiannon Tudor Edwards,5 Seow Tien Yeo,5 James Bainbridge,2 David Hopkins6 and Beverley White-Alao4

1National Institute for Health Research Clinical Research Facility, Moorfields Biomedical Research Centre, London, UK
2University College London Institute of Ophthalmology, London, UK
3Imperial Clinical Trials Unit, School of Public Health, Imperial College London, London, UK
4King’s Clinical Trials Unit King’s College London, London, UK
5Centre for Health Economics and Medicines Evaluation, Bangor University, Bangor, UK
6Department of Diabetes and Endocrinology, King’s College Hospital NHS Foundation Trust, London, UK

*Corresponding author Sobha.sivaprasad@moorfields.nhs.uk

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Plain English summary

Diabetes mellitus causes small blood vessels in the eye to close, starving the retina of oxygen. To attempt to repair the situation, the retina produces a protein, vascular endothelial growth factor (VEGF), that promotes the growth of new blood vessels. These new blood vessels have a high risk of bleeding and can pull the retina, causing retinal detachment. This stage of diabetic eye disease is called proliferative diabetic retinopathy (PDR) and can result in severe loss of eyesight. The current standard of care for this condition is panretinal photocoagulation (PRP), which involves destroying the retina that is starved of oxygen with a laser so that the demand for oxygen is reduced, which will in turn cause the retinal vessels to shrink, disappear or stop growing. However, the destruction of the retina with a laser is associated with adverse events on visual function. Therefore, better treatment approaches are required for this condition. Injections of anti-VEGF agents into the eye are routinely used in people with diabetes mellitus who suffer from diabetic macular oedema. In this study, we tested whether or not aflibercept, the most recently licensed anti-VEGF agent, could be used as an alternative to PRP for PDR.

We randomly allocated 232 participants from 22 NHS hospitals to receive either intravitreal aflibercept injections or PRP and compared the clinical effectiveness and cost-effectiveness outcomes.

From a public sector multiagency perspective that covers health and social care services, at an increased cost, participants treated with aflibercept had better outcomes for PRP in terms of visual acuity, more frequent regression of new vessels and fewer complications. As the study was only for 52 weeks, there is uncertainty about the need for further aflibercept in subsequent years. Long-term studies are required to understand the outcomes and cost implications of treating patients with anti-VEGF treatment for this condition for many years.

Headlines

Intravitreal aflibercept injections provided superior visual acuity and other positive clinical outcomes at 52 weeks compared with PRP in patients with PDR. If society is willing to pay £1400 for an additional 1-point improvement in best corrected visual acuity, then aflibercept has a 56.6% probability of being cost-effective at the list price of £816. From 20% through to 100% Patient Access Scheme, results showed 100% probability of aflibercept being cost-effective at the hypothetical societal willingness-to-pay threshold of £1400.
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