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Cheaper alternative to licensed drug for treating eye disease has similar side-effects

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Health policies which favour using ranibizumab for treating eye disease in older people over safety concerns for a cheaper alternative should take account of a new Cochrane Review published today. The researchers looked at the results of studies which compared the safety of two drugs used for treating age-related macular degeneration, ranibizumab and bevacizumab. Contrary to what was argued by some experts the review has found that the cheaper drug, bevacizumab, does not appear to increase deaths or serious side-effects compared with ranibizumab in people with neovascular age-related macular degeneration.

Neovascular macular degeneration is a progressive and chronic disease of the eye, and a leading cause of blindness in older people. About one in 10 people with macular degeneration suffers legal blindness. Bevacizumab is a drug that has been developed to treat cancer, while ranibizumab is marketed specifically for age-related macular degeneration. The two drugs are better known by their brand names Avastin (bevacizumab) and Lucentis (ranibizumab). The authors conclude that health policies that favour the much more costly ranibizumab instead of bevacizumab for macular degeneration, for reasons of safety, are not supported by current randomised controlled trial evidence. A larger Cochrane Review, which will assess additional sources of evidence, is now planned to help reduce the remaining uncertainties around the relative benefits and safety of these drugs.

Bevacizumab and ranibizumab are related biological drugs that work to prevent the abnormal growth and swelling of blood vessels that are

characteristic signs of macular degeneration. Although the beneficial effects of the two drugs are believed to be similar, only ranibizumab has been licensed as a treatment for macular degeneration; bevacizumab is currently approved only as a cancer therapy. Despite this, an unlicensed preparation of bevacizumab is often used off-label as treatment for macular degeneration, because it is cheaper than ranibizumab. It has been suggested that the two drugs have different safety profiles, such that bevacizumab might cause more systemic harms, and the review investigated this concern.

Lorenzo Moja, from the University of Milan, stated "This review represents an important step forward in the knowledge about differences in systemic harms between bevacizumab and ranibizumab and mitigate past disputes around evidence. The review authors were able to collect evidence from nine trials, including three unpublished studies, while most other reviews focus primarily on published data". He continues "This result was possible through the collaborative effort of researchers across several countries (France, Germany, Italy, UK, and USA), many of who were involved in the original trials. It shows a remarkable level of commitment of trialists and healthcare systems to answer an important clinical question. I am unaware of other examples with such a large number of head-to-head non-industry sponsored RCTs".

Editor in Chief of *The Cochrane Library*, Dr David Tovey, added "This review addresses a question of immense importance to health systems in many countries. One of the many considerations in decision-making at policy level is not just understanding how effective treatments are, but also weighing up evidence of their safety."

The review included nine randomised controlled trials (RCTs), none of which were supported by manufacturers of either treatment, involving a total of 3665 participants, comparing bevacizumab with ranibizumab. The drugs were given for up to two years. The review found the systemic

safety of bevacizumab for macular degeneration appeared to be similar to that of ranibizumab, except for gastrointestinal disorders. Although no statistically significant differences between the treatments were found, the review does not exclude the possibility that either treatment is less harmful than the other. The researchers estimated that if 1000 people were treated with ranibizumab for one to two years, 34 would die; if treated instead with bevacizumab, between 27 and 53 would die. If 1000 people were treated with ranibizumab, 222 would experience one or more serious systemic adverse events. If 1000 people were treated instead with bevacizumab, between 200 and 291 would experience such an event.

They rated the overall quality of the evidence as low to moderate because of the uncertainty of the findings, and due to other study limitations. Additionally, the review authors indicated that they could not fully assess the quality of three of the studies as they had not yet been published.

More information: Moja L, Lucenteforte E, Kwag KH, Bertele V, Campomori A, Chakravarthy U, D'Amico R, Dickersin K, Kodjikian L, Lindsley K, Loke Y, Maguire M, Martin DF, Mugelli A, Mühlbauer B, Püntmann I, Reeves B, Rogers C, Schmucker C, Subramanian ML, Virgili G. Systemic safety of bevacizumab versus ranibizumab for neovascular age-related macular degeneration. *Cochrane Database of Systematic Reviews* 2014, Issue 9. Art. No.: CD011230. DOI: 10.1002/14651858.CD011230.pub2

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