"COST EFFECTIVENESS OF BIOSIMILAR ONGAVIA IN NEW AND STABLE TREATED EYES IN VARIOUS RETINAL CONDITIONS AS COMPARED TO LUCENTIS"

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INTRODUCTION

Ongavia® is a licensed Ranibizumab biosimilar available in UK for the treatment of:

- Neovascular (wet) age-related macular degeneration (AMD)
- Proliferative diabetic retinopathy (PDR)
- Visual impairment due to diabetic macular oedema (DME)
- Visual impairment due to choroidal neovascularisation (CNV)
- Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

These are the same licensed indications in adults as the originator product, Lucentis® . It contains the same excipients as Lucentis. It has the same storage conditions as Lucentis. Ongavia has a shelf life of 2 years. Lucentis products have a shelf life of 3 years. It does not come pre-filled and has to be prepared in line with local and national guidelines. The dosing regimen for Ongavia is the same as Lucentis (0.5mg, corresponding to an injection volume of 0.05mL, given as a single intravitreal injection). One injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity. Three or more consecutive monthly injections may be needed. When maximum visual acuity is achieved and/or there are no signs of disease activity, treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur.

BACKGROUND

Biosimilars are the compounds which have small structural differences from the original licensed products but they do not alter the medicine safety, efficacy or reaction with the body's immune system. However they are much cheaper than the original licensed products. Ranibizumab has long been proven efficient in treating various retinal pathologies associated with retinal leakage. Since these conditions require treatments over for long periods of time, these have a profound cost impact on NHS. In our study we compared cost-effectiveness of biosimilar (Ongavia)

STUDY DESIGN

Retrospective cross sectional study

SAMPLE SIZE

123 eyes: 65 AMD, 25 DMO, 32 RVO, 1 myopic CNV

END POINTS

Primary: OCT changes, Secondary: V/A

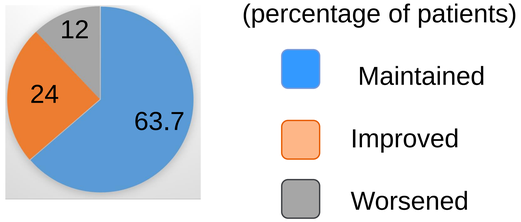
SAFETY FACTORS

Any adverse effects like

- Endophthalmitis
- Retinal vasculitis
- Systemic hemodynamic incidence

RESULTS

Out of 123 eyes, 102 were new eyes (82.9%) and 21 were switched (17.07%). 38 dried out (37.25%)of 102 new eyes, 60 remained stable (58.82%) while 4 got worse (3.92%)Those which were switched all remained stable.
BCVA was maintained in 63.7% eyes, improved in 24.2% eyes and worsened in 12.1% eyes.



DISCUSSION

Several randomized controlled trials have shown that Ongavia was clinically equivalent to Lucentis when 0.5mg was given by intravitreal injection every 4 weeks for up to 12 months. The results support Ongavia equivalence to the reference product Lucentis. The frequency and type of ocular adverse effects and immunogenicity were similar.

NICE guidance on treatment of ARMD published in 2018 states that no clinically significant differences in effectiveness and safety of aflibercept, bevacizumab and ranibizumab were seen in the trials considered. Therefore, comparable regimes will be more cost effective if the agent has lower net acquisition, administration and monitoring costs. Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to the biosimilar. Biosimilars do not require a separate or additional Technology Appraisal.

Lucentis and Eylea are available as pre-filled syringes. Ongavia however, requires preparation prior to administration and this will need to be considered when planning clinic time. Staff training may also need to be considered.

Both Ongavia and Eylea have different doses and treatment intervals. This is important to consider when planning clinic capacity, particularly if patients are switched from Eylea to Ongavia

CONCLUSION

Biosimilars are effective alternative to original licensed product in terms of efficacy and safety and a viable choice due to being cost effective.

REFERENCES

1. Summary of Product Characteristics. Ongavia (ranibizumab) 10mg/ml solution for injection. Teva UK Ltd. https://www.medicines.org.uk/emc/product/13885 date of revision of text: 11/07/22 (accessed 11/07/22)
2. Summary of Product Characteristics. Lucentis (ranibizumab) 10mg/ml solution for injection. Novartis Pharmaceuticals UK Ltd. https://www.medicines.org.uk/emc/product/307/smpc date of revision of text: 01/04/22 (accessed 11/07/22)
3. Summary of Product Characteristics. Lucentis (ranibizumab) 10mg/ml solution for injection in pre-filled syringe. Novartis Pharmaceuticals UK Ltd. https://www.medicines.org.uk/emc/product/5418/smpc date of revision of text: 01/04/22 (accessed 11/07/22)
4. The Royal College of Ophthalmologists (2018) Intravitreal injection therapy. Ophthalmic Service Guidance. Available at https://www.rcophth.ac.uk/wp content/uploads/2022/02/Intravitreal-Injection-Therapy-August-2018-1.pdf
5. Holz FG, Oleksy P, Ricci F, Kaiser PK, Kiefer J, Schmitz-Valckenberg S; COLUMBUS AMD Study Group. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. Ophthalmology. 2022 Jan;129(1):54-63. doi:10.1016/j.ophtha.2021.04.031. Epub 2021 May 3. PMID: 33957183
6. Fenner S - Specialist Pharmacy Service. (2022). The licence and supporting evidence for ranibizumab biosimilar. [online] Available at: https://www.sps.nhs.uk/articles/the-licence-and-supporting-evidence-for ranibizumab-biosimilar/#:~:text=ongavia [Accessed 12 Jul. 2022].
7. National Institute for Health and Care Excellence (2013) Ranibizumab for treating diabetic macular oedema. NICE Technology appraisal [TA274]. Available at https://www.nice.org.uk/guidance/ta274 accessed 11/07/22
8. National Institute for Health and Care Excellence (2013) Ranibizumab for treating choroidal neovascularisation associated with pathological myopia. NICE Technology appraisal [TA298]. Available at https://www.nice.org.uk/guidance/ta298 accessed 11/07/22
9. National Institute for Health and Care Excellence (2013) Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion. NICE Technology appraisal [TA283]. Available at https://www.nice.org.uk/guidance/ta283 accessed 11/07/22 10
10. National Institute for Health and Care Excellence (2018) Age-related macular degeneration. NICE Guideline [NG82]. Available at https://www.nice.org.uk/guidance/ng82 accessed 11/07/22 14 July 2022 Version 1
11. National Institute for Health and Care Excellence (2020) Ranibizumab for treating diabetic retinopathy (terminated appraisal). NICE Technology appraisal [TA637]. Available at https://www.nice.org.uk/guidance/ta637 accessed 11/07/22
12. National Institute for Health and Care Excellence (2022) Diabetic retinopathy. NICE Guideline in development [GID-NG10256]. Available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10256 accessed 11/07/22
13. The Royal College of Ophthalmologists (2021) Age Related Macular Degeneration Services. Commissioning Guidance. Available at https://www.rcophth.ac.uk/wp content/uploads/2021/08/AMD-Commissioning-Guidance-Full-June-2021.pdf