



Extended Research Article

Pramipexole in addition to mood stabilisers for treatment-resistant bipolar depression: the PAX-BD randomised double-blind placebo-controlled trial

Hamish McAllister-Williams,^{1,2,3*} Nicola Goudie,⁴ Lumbini Azim,³ Victoria Bartle,³ Michael Berger,⁵ Chrissie Butcher,⁴ Thomas Chadwick,⁴ Emily Clare,³ Paul Courtney,³ Lyndsey Dixon,³ Nichola Duffelen,³ Tony Fouweather,⁴ William Gann,⁶ John Geddes,⁷ Sumeet Gupta,⁸ Beth Hall,³ Timea Helter,⁵ Paul Hindmarch,³ Eva-Maria Holstein,⁴ Ward Lawrence,⁹ Phil Mawson,⁴ Iain McKinnon,^{3,4} Adam Milne,⁴ Aisling Molloy,³ Abigail Moore,⁴ Richard Morriss,¹⁰ Anisha Nakulan,³ Judit Simon,^{5,7} Daniel Smith,¹¹ Bryony Stokes-Crossley,³ Paul Stokes,¹² Andrew Swain,⁴ Zoë Walmsley,⁴ Christopher Weetman,⁴ Allan H Young¹² and Stuart Watson^{1,2,3}

¹Translational and Clinical Research Institute, Newcastle University, Newcastle upon Tyne, UK

²Northern Centre for Mood Disorders, Newcastle University, Newcastle upon Tyne, UK

³Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, Newcastle upon Tyne, UK

⁴Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, UK

⁵Medical University of Vienna, Vienna, Austria

⁶Sheffield Health and Social Care NHS Foundation Trust, Sheffield, UK

⁷University of Oxford, Oxford, UK

⁸Tees, Esk and Wear Valleys NHS Foundation Trust, Darlington, UK

⁹Surrey and Borders Partnership NHS Trust, Leatherhead, UK

¹⁰University of Nottingham, Nottingham, UK

¹¹Edinburgh University, Edinburgh, UK

¹²King's College London, London, UK

*Corresponding author hamish.mcallister-williams@newcastle.ac.uk

Published May 2025

DOI: 10.3310/HBFC1953

Plain language summary

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Health Technology Assessment 2025; Vol. 29: No. 21

DOI: 10.3310/HBFC1953

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Plain language summary

Patients with bipolar disorder have symptoms (depression or elevated mood) around 50% of the time and mostly these are depressive. There are few recommended treatments for bipolar depression, they do not always work, and often come with side effects like weight gain and drowsiness. There is a suggestion that pramipexole (currently used to treat Parkinson's disease) may help treat bipolar depression. The PAX-BD trial aimed to test this, as well as seeing if it is safe and cost-effective over 48 weeks.

Those eligible for the trial were randomly allocated to receive either pramipexole or placebo. Neither the treating team nor the participants knew which treatment they were receiving.

Unfortunately, only 39 participants entered the trial due to the trial being closed early. While pramipexole did lead to a greater reduction in depressive symptoms compared to placebo at 12 weeks, the difference was not statistically significant, possibly due to there being too few participants in the trial. However, there were some statistically significant beneficial effects of pramipexole on mood, everyday functioning and quality of life later in the trial. On the downside, pramipexole appeared to increase the risk that participants experienced symptoms of elevated mood. There was evidence that pramipexole may be a cost-effective treatment. However, because of the trial being small in size, the results are not definitive and we cannot conclude that pramipexole should routinely be used for people with bipolar depression. Further research is required to give a clearer answer.

A patient and public involvement group worked on the trial and provided valuable input into its design and conduct, and we learnt more about how such input can be improved in future trials. We also learnt more about what can help and hinder people taking part in studies like PAX-BD.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.5

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This article

The research reported in this issue of the journal was funded by the HTA programme as award number 16/154/01. The contractual start date was in April 2018. The draft manuscript began editorial review in June 2023 and was accepted for publication in August 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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