

Amisulpride augmentation in clozapine-unresponsive schizophrenia (AMICUS): a double-blind, placebo-controlled, randomised trial of clinical effectiveness and cost-effectiveness

Thomas RE Barnes,^{1,2*} Verity C Leeson,¹
Carol Paton,^{1,3} Louise Marston,^{4,5} Linda Davies,⁶
William Whittaker,⁶ David Osborn,^{7,8} Raj Kumar,⁹
Patrick Keown,^{10,11} Rameez Zafar,¹² Khalid Iqbal,¹³
Vineet Singh,¹⁴ Pavel Fridrich,¹⁵ Zachary Fitzgerald,¹⁶
Hemant Bagalkote,¹⁷ Peter M Haddad,^{18,19}
Mariwan Husni^{20,21} and Tim Amos^{22,23}

¹Centre for Mental Health, Imperial College London, London, UK

²West London Mental Health NHS Trust, London, UK

³Oxleas NHS Foundation Trust, London, UK

⁴Department of Primary Care and Population Health, University College London, London, UK

⁵PRIMENT Clinical Trials Unit, University College London, London, UK

⁶Centre for Health Economics, Institute of Population Health, University of Manchester, Manchester, UK

⁷Division of Psychiatry, University College London, London, UK

⁸Camden and Islington NHS Foundation Trust, London, UK

⁹Tees, Esk and Wear Valley NHS Foundation Trust, Billingham, UK

¹⁰Northumberland Tyne and Wear NHS Foundation Trust, Newcastle upon Tyne, UK

¹¹Institute of Neuroscience, Newcastle University, Newcastle upon Tyne, UK

¹²Lincolnshire Partnership NHS Foundation Trust, Lincoln, UK

¹³Bradford District Care Trust, Bradford, UK

¹⁴Derbyshire Healthcare NHS Foundation Trust, Derby, UK

¹⁵North Essex Partnership University NHS Foundation Trust, Chelmsford, UK

¹⁶Manchester Mental Health and Social Care NHS Trust, Manchester, UK

¹⁷Nottinghamshire Healthcare NHS Foundation Trust, Nottingham, UK

¹⁸Greater Manchester West Mental Health NHS Foundation Trust, Manchester, UK

¹⁹Institute of Brain, Behaviour and Mental Health, University of Manchester, Manchester, UK

²⁰Central and North West London NHS Foundation Trust, London, UK

²¹Northern Ontario School of Medicine, Sudbury, ON, Canada

²²Avon and Wiltshire Mental Health Partnership NHS Trust, Bristol, UK

²³School of Social and Community Medicine, University of Bristol, Bristol, UK

*Corresponding author t.r.barnes@imperial.ac.uk

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Plain English summary

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When schizophrenia has not improved with standard antipsychotic medication, a particular antipsychotic (clozapine) can sometimes work. If the response to treatment with clozapine on its own is insufficient, a second antipsychotic is sometimes added. However, despite several research studies addressing such a combination treatment, it is still uncertain whether or not it is worthwhile trying in clinical practice. Therefore, we carried out a trial comparing the effects of adding either an antipsychotic (amisulpride) or a dummy tablet (placebo) for 12 weeks in people with schizophrenia who had not been helped much by their clozapine treatment. We chose amisulpride because the way this medicine works may be complementary to that of clozapine, and it is less likely than some other antipsychotics to add to some of the characteristic side effects of clozapine, such as sedation, weight gain and changes in the levels of blood sugar and fats.

To avoid bias towards either amisulpride or placebo, no one knew which of these two medications any person was prescribed. Those people prescribed amisulpride proved to be a little more likely than those given placebo to have a 20% improvement in their symptoms by the end of the 12-week trial, although we did not manage to enrol enough people in our trial to be confident about this finding. More side effects, including heart symptoms, were reported by the people given the amisulpride and clozapine combination, which suggests that this treatment should be carefully monitored for safety and tolerability in both clinical and research settings.

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