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


Record Status
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Citation

Authors' objectives
The main objectives of the study were to establish the clinical effectiveness and cost-effectiveness of augmentation of clozapine medication with a second antipsychotic, amisulpride, for the management of treatment-resistant schizophrenia.

Authors' conclusions
The risk–benefit of amisulpride augmentation of clozapine for schizophrenia that has shown an insufficient response to a trial of clozapine monotherapy is worthy of further investigation in larger studies. The size and extent of the side effect burden identified for the amisulpride–clozapine combination may partly reflect the comprehensive assessment of side effects in this study. The design of future trials of such a treatment strategy should take into account that a clinical response may be not be evident within the 4- to 6-week follow-up period usually considered adequate in studies of antipsychotic treatment of acute psychotic episodes. Economic evaluation indicated the need for larger, longer-term studies to address uncertainty about the extent of savings because of amisulpride and impact on QALYs. The extent and nature of the side effect burden identified for the amisulpride–clozapine combination has implications for the nature and frequency of safety and tolerability monitoring of clozapine augmentation with a second antipsychotic in both clinical and research settings.

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