Clinical trial: First treatment for 'emotional flatness' associated with schizophrenia

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Results of a clinical trial seem to show the first effective treatment for the negative symptoms - withdrawal, lack of emotion, and apathy - associated with schizophrenia. This work is presented at the European College of Neuropsychopharmacology conference in Amsterdam.

Schizophrenia is one of the most common serious mental health conditions, with around 1 in 100 people experiencing schizophrenia in their lifetime. The main symptoms fall into 3 categories: positive symptoms, such as delusions and hallucinations; negative symptoms, such as lack of drive and social withdrawal; and cognitive symptoms, such as problems with attention and memory. The negative symptoms tend to persist, and don't respond well to current treatment. Effective medicines (antipsychotics) exist for positive symptoms, but negative symptoms and cognitive impairment do not respond well to the available treatments.

Now the results of a new Phase III clinical trial indicate that the negative symptoms may be treatable with a new investigational drug, cariprazine, which binds to the D2 and D3 dopamine receptor with D3 preference. The researchers, all from the Gedeon Richter pharmaceutical company which developed the drug, enrolled 461 men and women in a randomised, double-blind clinical trial, to compare cariprazine against risperidone (which is commonly used to treat schizophrenia). Patients were treated for 26 weeks, with 77.4% of enrolled patients completing the trial. Full details of the trial are given in the abstract.

The outcomes were measured using a special subscale of the PANSS scale (Positive and Negative Syndrome Scale) which is a standard method used for measuring symptom severity of patients with schizophrenia. After 26 weeks of treatment, it was found that cariprazine treatment group showed a statistically significant improvement in the PANSS-NFS scale relative to risperidone (-1.47; p=0.002). In addition to the effect on predominant negative symptoms of schizophrenia, patients who took cariprazine also performed significantly better on personal and social functioning than those who took risperidone. Full details of the trial are given in the abstract.

According to lead researcher Dr György Németh (Chief Medical Officer, Gedeon Richter):

"The positive symptoms of schizophrenia can be controlled by drugs, but this is the first study ever to show a significant effect of a compound on negative symptom compared to another antipsychotic. It seems that with cariprazine, we may be able to treat both the positive and negative symptoms with a single medication."

Commenting, ECNP Executive Committee Member Professor Andreas Meyer-Lindenberg said:

"Treatments for the negative symptoms of schizophrenia are still urgently needed as these are critical predictors for patient's recovery and reintegration. The current results suggest that D3-dopaminergic mechanisms may play a role in both causing and treating emotional flatness, which deserve further confirmation".

The trial was organised and supported by the Gedeon Richter pharmaceutical company, which developed cariprazine. The researchers report that the most frequent adverse events (incidence ?5%) across both treatments groups were insomnia, headache, akathisia, worsening of

schizophrenia symptoms, anxiety and somnolence. As this drug has not yet completed the approval process, no indication of the costs of the treatment is available.

Provided by European College of Neuropsychopharmacology