

Pimavanserin: Relief from psychosis in dementia, without devastating side-effects

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Clive Ballard, Professor of Age-Related Diseases, University of Exeter Medical School. Credit: University of Exeter

A new kind of antipsychotic has been found to relieve terrifying and disturbing symptoms suffered by millions of people with Alzheimer's disease worldwide.

New research led by the University of Exeter Medical School, and published today in *Lancet Neurology* found that pimavanserin significantly improves [psychosis symptoms](#) in [people](#) with the condition, without the devastating side-effects of currently-used antipsychotics. The research found an even greater benefit in those with the most severe psychotic symptoms.

Up to half of the 45 million people worldwide who are living with Alzheimer's [disease](#) will experience psychotic episodes, a figure that is even higher in some other forms of dementia. Psychosis is linked to a faster deterioration in dementia.

Currently there is no approved safe and effective treatment for these distressing symptoms. In people with dementia, widely-used antipsychotics lead to sedation, falls and can double the speed at which brain function deteriorates. Their use increases risk of falls, and leads to 1,660 unnecessary strokes and 1,800 unnecessary deaths in the UK every year. Despite all of these negative effects they have very little benefit in improving psychosis in people with dementia. Pimavanserin works differently to other antipsychotics, by blocking a very specific nerve receptor (5HT_{2A}) in the brain. Now, it has been found to effectively reduce symptoms of psychosis in people with Alzheimer's disease without the damaging effects of other antipsychotics.

Clive Ballard, Professor of Age-Related Diseases at the University of Exeter Medical School, who led the research, said: "Psychosis is a particularly terrifying symptom of Alzheimer's disease. People may experience paranoia, or see, hear or smell things that are not there. It's distressing both for those experiencing the delusions and for their carers.

"It's particularly encouraging that most benefit was seen in those with the most severe psychotic [symptom](#), as this group is most likely to be prescribed antipsychotics. We are talking about vulnerable elderly, frail

people who are suffering terrifying symptoms, being sedated with current antipsychotics even though it's well known that they cause terrible health issues and even death in people with dementia, and have very little benefit. We urgently need to do better by them, and our encouraging results provides hope. We're delighted that our results have led to a larger phase 3 clinical trial which is now ongoing." The findings are the result of a double-blind, placebo-controlled exploratory trial designed to evaluate the efficacy and safety of pimavanserin in 181 patients with Alzheimer's disease psychosis, with 90 of them given pimavanserin and 90 of them on a placebo. Its safety and efficacy in reducing psychotic symptoms in dementia is now being assessed in a larger-scale clinical trial in the US.

The results build on previous research that found pimavanserin was effective for people with dementia related to Parkinson's disease. Pimavanserin has been approved for use by the Food and Drug Administration (FDA) in the US for this purpose, but has not yet been submitted for approval to the European equivalent, the European Medicines Agency.

Previously, the Alzheimer's Society said it is "imperative" that it goes through European approval processes for Parkinson's Disease Dementia.

Pimavanserin is currently the subject of a Phase III trial in the US to assess its safety in a wider group, and to see if it can prevent relapse of [psychotic symptoms](#) in some of the most common forms of [dementia](#).

The paper, Evaluation of the efficacy, tolerability, and safety of pimavanserin versus placebo in patients with Alzheimer's disease and [psychosis](#): phase 2, randomised, placebo-controlled, double blind study, is published today in *Lancet Neurology*.

More information: Clive Ballard et al. Evaluation of the safety,

tolerability, and efficacy of pimavanserin versus placebo in patients with Alzheimer's disease psychosis: a phase 2, randomised, placebo-controlled, double-blind study, *The Lancet Neurology* (2018). DOI: 10.1016/S1474-4422(18)30039-5 , www.ncbi.nlm.nih.gov/pubmed/29452684

Provided by University of Exeter

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