

Promising phase II trial of new oral treatment for relapsing MS

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The results of a Phase II clinical trial looking at the effects of a new therapy, ozanimod, for relapsing MS has been published in the journal [Lancet Neurology](#).

Ozanimod is one of several medications currently under investigation that are in the same family as fingolimod (Gilenya) that is already available for relapsing MS. All of these medications act within the same biological pathway as fingolimod, but have slight modifications in the mechanisms of action that aim to improve the side effect profile, and some such as ozanimod aim to reduce the known effects of fingolimod on cardiovascular function and heart rate.

This trial of ozanimod included 258 people with relapsing MS recruited from 55 sites across Europe and the USA. The trial tested whether the treatment was effective in reducing new or newly active lesions on magnetic resonance imaging (MRI). A [Phase II trial](#) is primarily designed to study safety, identify side effects, and to gather preliminary data for signs of effectiveness of a new medication. The trial found that after 6 months of treatment, people receiving ozanimod had a substantial reduction in the number of gadolinium-enhancing lesions, compared to placebo.

Ozanimod was associated with few major side effects. Most commonly reported were nasopharyngitis (nose and throat inflammation), headache, and urinary tract infection. There were no reports of serious infections or cardiac events, or any cases of macular oedema.

This trial included a dose titration period, where participants are started on lower doses before increasing to higher doses of ozanimod over an 8-day period. This successfully prevented any cardiovascular side effects and the researchers report no sign of atrioventricular block (impaired electrical flow in the heart resulting in slowed heart beat).

The researchers reported that these results present good evidence to continue exploring ozanimod in the next stage of Phase III trials, which are currently underway. A Phase III trial is conducted in a much larger group of participants and is designed to obtain robust evidence for the effectiveness of a medication in reducing disease activity. Further results from the Phase III trial of ozanimod are expected in 2017.

An international Phase III trial of another medication in the same family, called siponimod, is currently ongoing for people with secondary progressive MS.