

Gilenya not effective for slowing disease progression in primary progressive MS

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Following our [earlier report](#) in 2014 of disappointing preliminary results from a phase III clinical trial of Gilenya (fingolimod) in people with primary progressive MS (PPMS), the full results of this trial have recently been published in prestigious medical journal [The Lancet](#).

Led by researchers from the Icahn School of Medicine at Mount Sinai in New York and the University College London Institute of Neurology in the UK, this study has furthered the initial reports indicating that fingolimod was not effective in slowing disease progression in people with primary progressive MS.

Primary progressive MS affects around 10% of people diagnosed with MS. It is characterised by none, or very few, of the acute attacks that are typical of relapsing-remitting MS. Instead people with this form of MS experience a gradual accumulation of disability from the beginning of their disease.

The phase III trial, known as INFORMS, included 970 people with primary progressive MS who were enrolled across 18 countries, including Australia. Patients were treated for at least three years, and were randomly allocated to receive either fingolimod or dummy tablets (placebo).

The primary aim of the trial was to assess whether fingolimod could delay or prevent an accumulation of disability over a three month period. Unfortunately, fingolimod did not show any benefits on slowing disease progression compared to placebo – participants in both groups showed continued disease progression throughout the three-year study.

The researchers did find that fingolimod was beneficial for reducing the frequency of relapses, and MRI scans showed that participants also had a 73% reduction in active MS lesions. This is similar to its effects in people with relapsing-remitting MS, and is consistent with early trials showing that fingolimod is effective for reducing the inflammatory components of the disease, rather than targeting the progressive components of the disease.

The lack of effects on disease progression is very disappointing news for the MS community who are frustrated by the current lack of treatments for progressive forms of MS.

However, as with all clinical trials it is crucial that both negative and positive results are published and examined in detail. Even a negative result can teach researchers more about the underlying disease processes and the mechanisms by which drugs work.

More widely, there is a considerable international push to fast-track treatment options for progressive MS. Accelerating research into treatments for the progressive forms of MS is the goal of the [International Progressive MS Alliance](#). Recently, international researchers announced promising results from a [Phase III trial of ocrelizumab](#), showing benefits for not only for relapsing-remitting but also for progressive MS.