New oral drug found to reduce relapses in multiple sclerosis patients

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A new oral drug has been shown in a large international clinical trial to significantly reduce the relapse rate of people with multiple sclerosis and to slow the progression of the disease.

The results of the Phase 3 trial of the drug teriflunomide were published in The New England Journal of Medicine on Thursday.

"This could be a safe, effective and convenient new therapy for multiple sclerosis,"said Dr. Paul O'Connor, the principal investigator for the study and director of the Multiple Sclerosis Clinic at St. Michael's Hospital in Toronto, the largest and one of the most active MS research clinics in Canada.

Multiple sclerosis (MS) is the most common disabling neurological disorder of young adults in Canada. In this condition, the immune system attacks the myelin sheath surrounding nerve cells. MS has traditionally been treated with injectable drugs, which are uncomfortable to use and have side effects. Only one other oral medication for MS has been approved by Health Canada and the U.S. Food and Drug Administration.

A Phase 3 trial is a randomized trial involving a large number of patients at multiple health-care centres that is designed to assess a medication's effectiveness and safety before it is approved for public use.

Dr. O'Connor's study involved 1,088 MS patients between the ages of 18 and 55 who had at least one relapse in the previous year or at least two

relapses in the previous two years. A relapse is either the appearance of a new symptom of the disease – such as weakness, numbness, loss of vision -- or a worsening of previous symptoms that had been stable.

Each day, one-third of the patients received a placebo; one-third received a 7-mg dose of teriflunomide; and one-third received 14 mg. of the drug. The study lasted just over two years.

The study found a 31-per-cent reduction in relapses in patients taking the drug – 31.2 per cent for those taking 7mg and 31.5 per cent for those taking 14 mg.

The drug also increased the length of time before a patient relapsed and more patients taking it remained free of relapses.

Progression of the disease was also reduced by almost 30 per cent among those taking the 14-mg dose.

MRIs showed that patients taking 14mg of teriflunomide had a 69-per-cent reduction in the number of new abnormalities in their brains caused by MS. The reduction was 48 per cent for those on the lower dose of the drug.

Teriflunomide works by attaching itself to an enzyme that is important for the synthesis of DNA. That prevents rapidly dividing cells in the immune system from dividing and attacking the central nervous system.

Dr. O'Connor said patients in the clinical trials tolerated the drug well. There was no difference in the rate of serious side effects between patients taking the placebo and those taking teriflunomide and there were no deaths during the study. Side effects that were more common in the teriflunomide groups were diarrhea, nausea, and mild hair loss.

Teriflunomide is manufactured by Sanofi, which funded the clinical trial. Further studies are underway to replicate the work of Dr. O'Connor's group and to determine the long term effectiveness and safety of the drug.

Provided by St. Michael's Hospital