PROJECT INFORMATION

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Comparing Medicines to Help Patients with Multiple Sclerosis Feel Less Fatigued -- The TRIUMPHANT-MS Study

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What was the research about?

Multiple sclerosis, or MS, is an illness that affects the central nervous system. Fatigue is a common and disabling symptom of MS.

In this study, the research team wanted to learn how well three commonly used medicines work to help patients with MS feel less fatigued and improve quality of life. The medicines were amantadine, methylphenidate, and modafinil. The team compared these medicines with a placebo. A placebo is a pill with no active ingredients. Using a placebo helps researchers learn if results are due to a medicine or chance.

Patients took each of the medicines and the placebo in a specific order over seven to eight months.

The research team also looked at whether patients took the medicines as prescribed and if they had adverse events. An adverse event is when a medicine causes harm; an example is an allergic reaction.

What were the results?

The three medicines didn't help patients feel less fatigued or sleepy or improve quality of life better than the placebo.

The percentage of patients who stopped taking each medicine was 6 percent for amantadine, 5 percent for methylphenidate, 8 percent for modafinil, and 3 percent for placebo.

Compared with placebo, more patients who took the medicines reported adverse events. The percentage of patients who reported at least one adverse event was 39 percent for amantadine, 40 percent for methylphenidate and for modafinil, and 31 percent for placebo.

Who was in the study?

The study included 141 adults with MS and fatigue. Of these, 76 percent were White, 14 percent were African American, 10 percent were another race, and 1 percent were Asian; 11 percent were Hispanic. The average age was 47, and 77 percent were women.

What did the research team do?

The research team assigned patients by chance to take the medicines in one of four sequences. Patients started with one medicine and took it for six weeks. Before starting the next medicine, patients stopped taking medicine for two weeks. Patients repeated this process for all three medicines and the placebo.

All patients had a screening visit at one of two health centers; the centers were in Maryland and California. Five weeks after patients started each medicine, they completed online surveys about fatigue, sleepiness, and quality of life. To learn if patients took the medicine as prescribed or had adverse events, the research team contacted patients five times by phone, email, or text during the time they were taking each medicine.

Patients with MS, doctors, an MS specialist, and a member of an advocacy group helped plan the study.

What were the limits of the study?

The study took place at two treatment centers. Patients took medicines for six weeks. Results may differ in other places or with longer-term use of the medicines.

Future research could look at other ways to help patients with MS feel less fatigued.

How can people use the results?

Patients with MS and their doctors can use these results when considering ways to treat fatigue.

To learn more about this project, visit www.pcori.org/Nourbakhsh359.