

Study investigates risk when discontinuing therapy for MS patients over 55

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An article published in the *The Lancet Neurology* journal evaluates the risk of recurrence of active disease in older patients with multiple sclerosis after discontinuing disease-modifying therapies.

Multiple sclerosis (MS) is a chronic illness, often presenting in young adulthood. Most commonly, at onset, individuals have acute attacks, or relapses, of intermittent new neurological symptoms such as vision changes, numbness, and weakness that may come and go, seemingly randomly, and then remit completely or incompletely. These are associated with magnetic resonance imaging (MRI) changes in the brain or spine.

Over time, as people age, new attacks and MRI changes become less common, and either patients stabilize, or they may go into a phase of slow progressive neurological disability with minimal MRI changes.

There is no cure for MS, but there are now over 20 disease-modifying therapies (DMTs) that may substantially diminish the risks of new attacks and MRI changes. Most of the DMTs have been approved after studying only patients 55 and under, and these medications appear to have greatest impacts on younger patients with recent relapses, and modest effects on slowing progressive disability, especially in older patients. Thus, benefits in older patients remain unclear, while risks related to the DMTs may increase with age. Whether it is reasonable to stop using the DMTs as people age remains an important, unanswered question.

The article reports the results of a clinical trial known as DISCOMS, the first randomized, controlled, observer-blinded trial of discontinuation of MS DMTs. Between May 2017 and February 2020, researchers recruited 259 participants over 55 who had not had an acute MS relapse for at least five years and no new MRI lesion for at least three years from 19 MS centers in the United States. Using any new relapse or MRI scan



change over two years as the main outcome, the study asked whether it was non-inferior to discontinue compared to staying on DMT.

Only 22/259 (6/128 in the continue group and 16/131 in the discontinue group) total individuals had a new event (relapse or MRI scan change). By this measure, the researchers were unable to show non-inferiority, i.e. it could be inferior to stop DMT, noting that 15/22 of the new events were 1-2 new MRI lesions unaccompanied by any relapse or change in disability, and only four (one continue, three discontinue) participants had an acute relapse. There also was no increase in disability, symptom scores, cognitive tests, or adverse events in those discontinuing DMT.

John R. Corboy, MD, professor of neurology at the University of Colorado School of Medicine, is the lead investigator and primary author of the article. "Our study addresses important concerns about the risks and benefits of disease-modifying therapies as people age. The primary objective of our study was to identify whether discontinuation is safe to consider for older patients with multiple sclerosis and no recent relapse or new MRI activity, and our goal was to provide an estimate of disease recurrence in this context," Corboy says.

He and his colleagues concluded that, while they were unable to show non-inferiority by this primary outcome, many patients 55 and older who have not had a relapse for five or more years might feel that the low risk of new clinical activity makes a personal discontinuation trial a reasonable option for them.

"This study will aid decision-making when <u>health care providers</u> and people with multiple sclerosis discuss potential disease-modifying therapy discontinuation as patients age," Corboy says.

More information: John R Corboy et al, Risk of new disease activity in patients with multiple sclerosis who continue or discontinue disease-



modifying therapies (DISCOMS): a multicentre, randomised, singleblind, phase 4, non-inferiority trial, *The Lancet Neurology* (2023). DOI: 10.1016/S1474-4422(23)00154-0

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