

CANCER RISK IN MULTIPLE SCLEROSIS PATIENTS TAKING CLADRIBINE

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Cladribine ABN abstract

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Cancer risk in people with Multiple Sclerosis taking cladribine

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Background: A large phase III trial (CLARITY) of oral cladribine (Movectro) in people with relapsing-remitting multiple sclerosis (pwRRMS) reported significant efficacy. However, a suspected cancer risk was key for the rejection of Movectro by the European Medicines Agency in 2010. We compared the cancer risk of Movectro with other disease-modifying therapies (DMTs).

Methods: Phase III trials of approved DMTs for pwRRMS were identified. Fisher's exact test was used to compare cancer rates.

Results: Twelve trials were included. Study heterogeneity was not significant. The CLARITY placebo group had a lower cancer rate (0%) compared to all other placebo groups (1.19%), $p=0.0159$. The cancer rate in the CLARITY treatment group (1.13%) was not increased compared to all other treatment groups (0.6%), $p=0.1139$. The CLARITY placebo group had a lower cancer rate compared to the recently completed trial of Movectro in people clinically isolated syndrome suggestive of demyelination (ORACLE), $p=0.0012$. In contrast, no difference was detected between cancer rates in the treatment groups of CLARITY vs ORACLE ($p=1$).

Conclusion: Movectro does not increase cancer risk in pwRRMS. Long term follow-up will help determining the cancer risk of all DMTs. Given its efficacy, tolerability and convenience cladribine should be reconsidered for treatment in pwRRMS.