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 with 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 determine the cancer risk of all DMTs. Given its efficacy, tolerability and convenience cladribine should be reconsidered for treatment in pwRRMS.