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# Cladribine vs Rituximab in Relapsing-Remitting Multiple Sclerosis: A Parallel Cohort Study on Comparative Long-Term Effectiveness

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**Introduction:** Følsomhet Intern (gul)

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Long-term comparative studies of high-efficacy therapies for relapsing-remitting multiple sclerosis (RRMS) are lacking, especially those including cladribine.

**Objectives/Aims:**

To compare long-term effectiveness and safety of rituximab with cladribine in patients with RRMS.

**Methods:**

We conducted a parallel cohort study on data from The Norwegian MS Registry. Adult patients with RRMS who initiated treatment on cladribine or rituximab at two university hospitals in Norway between May 15, 2018, and October 15, 2019, were included. End of follow-up was August 31, 2023. An observation analog of the intention-to-treat effect was estimated for the time-to-event outcomes, using the Kaplan-Meier estimator. We adjusted for baseline confounding using propensity score-weighting. Primary outcome was time to first new or enhancing MS-lesions on brain magnetic resonance imaging (MRI). Secondary outcomes were time to the first relapse; time to discontinuation of treatment or to third dose of cladribine; change in Expanded disability status scale (EDSS) score; proportion of patients with no evidence of disease activity (NEDA-3); and side-effects.

**Results:**

A total of 300 patients (cladribine; n = 132, rituximab; n = 168) were included and followed for a median of 4.5 years. The risk ratio (RR) of new MRI disease activity at 6 months was 2.5 for patients treated with cladribine compared to rituximab (37% [95% CI: 28-45] for cladribine and 15% [95% CI: 9.8-21] for rituximab). At 4 years, the RR had increased to 2.7 (58% [95% CI: 49–66] for cladribine and 21% [95% CI: 15 – 27] for rituximab). Adjusted analysis confirmed this finding (62% [95% CI: 47–72] for cladribine and 21% [95% CI: 15-27] for rituximab). The adjusted difference in average time to MRI disease activity was 14.1 months (95% CI: 7.99–20.3). At 4 years, patients treated with cladribine also had higher risk of relapses (17% [95% CI: 11-24] for cladribine and 6.0% [95% CI: 2.3–9.5] for rituximab), discontinuation of treatment and EDSS worsening, and a lower probability of NEDA-3. Results regarding side effects are currently being analyzed and will be presented

at the congress.

**Conclusion:**

Patients treated with cladribine had higher risks of MRI and clinical disease activity compared with patients treated with rituximab during a median follow-up of 4.5 years. Results from the ongoing randomized clinical trial, the NOR-MS trial (NCT04121403) studying non-inferiority of rituximab to cladribine, will complement our findings.

**Disclosures:**

Brit Ellen Rød: nothing to disclose.