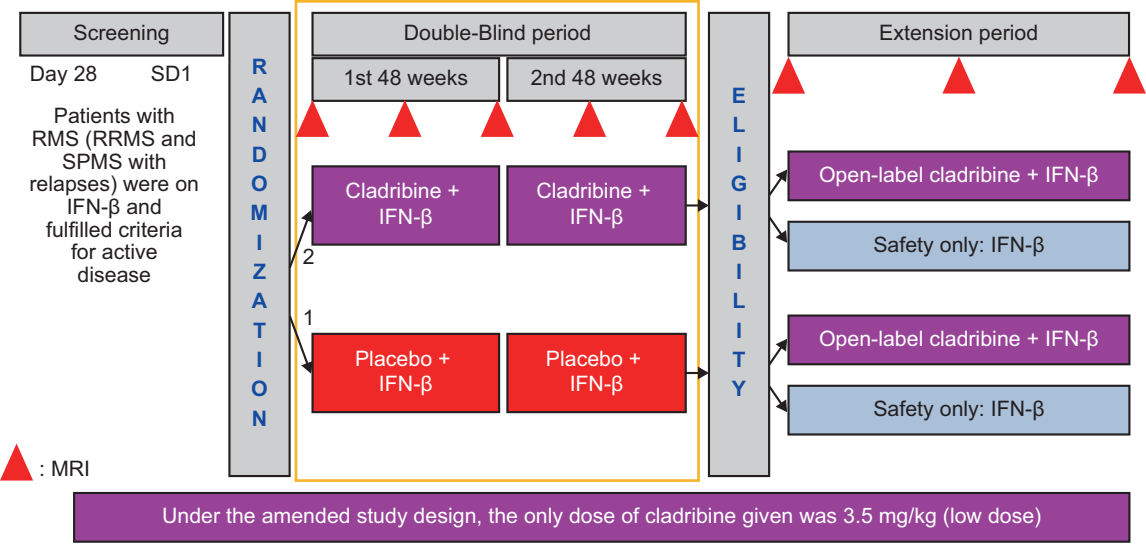
Screening
Day 28
SD1
Patients with RMS (RRMS and SPMS with relapses) were on IFN-β and fulfilled criteria for active disease
RANDOMIZATION
Double-Blind period
1st 48 weeks
2nd 48 weeks
Cladribine + IFN-β
Cladribine + IFN-β
2
1
Placebo + IFN-β
Placebo + IFN-β
ELIGIBILITY
Extension period
Open-label cladribine + IFN-β
Safety only: IFN-β
Open-label cladribine + IFN-β
Safety only: IFN-β
: MRI
Under the amended study design, the only dose of cladribine given was 3.5 mg/kg (low dose)
EDSS was assessed every 3 months