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Title: Meta-analysis of Randomized Placebo Control Trials in Multiple Sclerosis

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Background and Objective: The era of placebo-controlled trials in MS came to end, as it's no longer considered ethical to randomize patients to placebo when we have disease modifying therapy of proven efficacy. Our aim is to pool the annualized relapse rate ARR from all placebo MS trials and to estimate a prediction model for disease severity based on different patient and disease characteristics.

Method: From 1984 until 2012, 69 randomized placebo-controlled trials were done on MS related therapies. These studies were assessed for inclusion in the meta-analysis based on certain inclusion criteria. Important patients and study characteristics were retrieved, including primary outcome of the study, patients demographics ,assumed annualized relapse rate (ARR), baseline (ARR) , calculated ARR, Expanded disability scale score (EDSS) at baseline and at the end of follow up, as well as number and volume of MRI lesions.

Result: 5324 patients were followed up for an average period of 16.15 months with total drop out of 665(12.49%) patients. MRI related outcomes and EDSS were the primary endpoints in 26 and 7 trials, respectively. We included only 30 trials for quantitative analysis which had ARR with at least the 95% confidence interval or the mean ARR with the standard deviation. The calculated ARR from the 30 trials (3112 patients) is 2.56 (95% confidence interval [CI] =2.09-3.15). It was not possible to create a relapse-rate predicting model.

Conclusion: The calculated ARR in the pooled placebo groups could be used as good reference point for use in future clinical trials, where it would be no longer acceptable to randomize patients to a placebo arm. This is pivotal for calculating sample size and planning randomized control trials. Failure of making a prediction model could be at least partially related to the heterogeneity of MS patients cohorts.