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Explaining temporal trends in annualized relapse rates in placebo groups of randomized controlled trials in relapsing multiple sclerosis: systematic review and meta-regression

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Background: Recent studies have shown a decrease in annualised relapse rates (ARRs) in placebo groups of randomised controlled trials (RCTs) in relapsing multiple sclerosis (RMS).
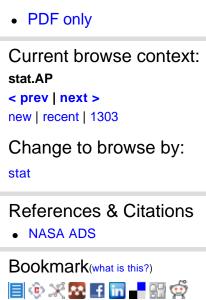
Methods: We conducted a systematic literature search of RCTs in RMS. Data on eligibility criteria and baseline characteristics were extracted and tested for significant trends over time. A meta-regression was conducted to estimate their contribution to the decrease of trial ARRs over time.

Results: We identified 56 studies. Patient age at baseline ($p < 0.001$), mean duration of multiple sclerosis (MS) at baseline ($p = 0.048$), size of treatment groups ($p = 0.003$), Oxford Quality Scale scores ($p = 0.021$), and the number of eligibility criteria ($p<0.001$) increased significantly, whereas pre-trial ARR ($p = 0.001$), the time span over which pre-trial ARR was calculated ($p < 0.001$), and the duration of placebo-controlled follow-up ($p = 0.006$) decreased significantly over time. In meta-regression of trial placebo ARR, the temporal trend was found to be insignificant, with major factors explaining the variation: pre-trial ARR, the number of years used to calculate pre-trial ARR and study duration. Conclusion: The observed decline in trial ARRs may result from decreasing pre-trial ARRs and a shorter time period over which pre-trial ARRs were calculated. Increasing patient age and duration of illness may also contribute.

Submission history

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