

How Transparent are Migraine Clinical Trials? RReMiT

Repository of Registered Migraine Trials

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ABSTRACT:

Transparency in research requires public access to unbiased information prior to trial initiation, and openly available results upon study completion. RReMiT is a global snapshot of registered migraine clinical trials and scorecard of results availability via the peer-reviewed literature, registry databases, and grey literature. The 295 unique clinical trials identified employed 447 investigational agents, with 30% of 154 acute migraine trials and 11% of 141 migraine prophylaxis trials testing combinations of agents. The most frequently studied categories in acute migraine trials were triptans, NSAIDs, antiemetics, CGRP antagonists, and acetaminophen. Migraine prophylaxis trials frequently studied anticonvulsants, beta-blockers, complementary/alternative therapies, antidepressants, and botulinum toxin. Overall, 237 trials were eligible for a results search. Of 163 trials completed at least 12 months earlier, 57% had peer-reviewed literature results, and registries/grey literature added another 13%. Using logistic regression analysis, studies with a sample size below the median of 141 subjects were significantly less likely to have results, but the dominant factor associated with availability of results was time since study completion. In unadjusted models, trials registered on *ClinicalTrials.gov* and trials with industry primary sponsorship were significantly more likely to have results. Recently completed trials rarely have publicly available results; two years after completion the peer-reviewed literature contains results for less than 60% of completed migraine trials. To avoid bias, evidence-based therapy algorithms should consider factors affecting results availability. As negative trials are less likely to be published, special caution should be exercised before recommending a therapy with a high proportion of missing trial results.