

Initial and Maintenance Naltrexone Treatment for Alcohol Dependence Using Primary Care vs Specialty Care

A Nested Sequence of 3 Randomized Trials

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Background Naltrexone may improve success in primary care treatment of alcohol dependence (AD). This study tests naltrexone and primary care management (PCM) vs naltrexone and cognitive behavior therapy (CBT) and tests naltrexone maintenance among patients who respond to an initial course of naltrexone combined with PCM vs CBT.

Methods A nested sequence of 3 randomized trials was conducted. In study 1, 197 subjects with AD participated in a 10-week comparison of PCM and naltrexone (50 mg/d) vs CBT and naltrexone (50 mg/d). In study 2, 53 PCM responders from study 1 continued in a 24-week placebo-controlled study of maintenance naltrexone. In study 3, 60 CBT responders from study 1 continued in a 24-week placebo-controlled study of maintenance naltrexone and CBT.

Results Study 1: No difference in the response to treatment; 84.1% (74/88) of the PCM patients and 86.5% (77/89) of the CBT patients avoided persistent heavy drinking. Percentage of days abstinent (PDA) declined over time for PCM vs CBT ($P = .03$). Study 2: Higher response maintenance for PCM and naltrexone (21/26, 80.8%) vs PCM and placebo (14/27, 51.9%; $P = .03$) and PDA declined more for the placebo group ($P = .02$). Study 3: The differences between naltrexone vs placebo on maintenance of response (25/30, 83.3% vs 21/30, 70.0%) or PDA did not reach statistical significance.

Conclusions Naltrexone yielded comparable results during the initial 10 weeks of treatment when combined with PCM or CBT. Maintenance of improvement was enhanced by continued naltrexone treatment in the PCM but not in the CBT arm.