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Extended-Release Intramuscular Naltrexone

A Viewpoint by Henry R. Kranzler

University of Connecticut School of Medicine, Farmington, Connecticut, USA

Naltrexone, an opioid receptor antagonist, was first approved in the US in 1984 for the treatment of opioid dependence; 10 years later it was also approved for the treatment of alcohol dependence. However, naltrexone has not been widely prescribed for either disorder, at least in part because of inconsistent adherence with oral therapy. Over the past decade, efforts have been made to develop a long-acting parenteral naltrexone formulation in an effort to enhance adherence and provide sustained blood concentrations of the drug. In a recent phase III clinical trial,[1] an extended-release intramuscular formulation consisting of biodegradable microspheres and naltrexone, administered at a dosage of 380mg once monthly over a 6-month treatment period, significantly reduced the event rate of heavy drinking in alcohol-dependent individuals. Comparison of the 380mg dosage with the 190mg dosage (though the efficacy of only the former differed statistically significantly from placebo) yielded effects consistent with a dose-response relationship. Both dosages were well tolerated when administered monthly for as long as 18 months. Although additional research is needed to determine the optimal approach to the use of the extended-release formulation, the US FDA recently approved this formulation for the treatment of alcohol dependence in combination with psychosocial therapy.

Together with the FDA approval of acamprosate in 2004 (a medication that has long been used in Europe), the addition of an extended-release formulation of naltrexone to the existing approved treatments in the US (oral naltrexone and disulfiram, which was approved >50 years ago) will substantially increase the options available for the pharmacotherapy of alcohol dependence. These developments bode well for individuals with this disorder because although alcohol dependence is highly prevalent in the population, it often goes untreated. ▲

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Reference

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