

Meta-analysis finds evidence for nalmefene in the treatment of alcohol dependence is weak

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Currently available evidence from randomized controlled trials (RCT) does not support the use of nalmefene for harm reduction for people with alcohol dependence, according to a systematic review and metaanalysis (SRMA) published this week in *PLOS Medicine*. The study, conducted by Florian Naudet at INSERM, Centre Hospitalier Universitaire de Rennes, France also indicates that evidential support for the use of nalmefene to reduce alcohol consumption among this population is limited.

Nalmefene blocks the body's <u>opioid receptors</u> and reduces the craving for alcohol. The drug has mixed recommendations from health agencies and expert bodies for use in the treatment of <u>alcohol dependence</u>. Naudet and colleagues used SRMA to investigate the risks and benefits of nalmefene in the treatment of alcohol dependence in adults. The metaanalysis of five eligible RCTs (involving 2567 participants) found no differences between participants taking nalmefene versus those taking placebo in mortality after 6 months (Relative Risk = 0.39, 95% CI [0.08; 2.01]) or 1 year (RR = 0.98, 95% CI [0.04; 23.95]) of treatment, quality of life at 6 months (SF?36 physical component summary score: Mean Difference = 0.85, 95% CI [?0.32; 2.01]), or mental health (summary score MD = 1.01, 95% CI [?1.33; 3.34]). Participants taking nalmefene had fewer heavy drinking days at 6 months (MD = -1.65, 95% CI [?2.41; ?0.89]) and 1 year (MD = -1.60, 95% CI [?2.85; ?0.35]) of treatment than participants taking placebo, and their total alcohol consumption at 6



months was lower (SMD = -0.20, 95% CI [?0.30; ?0.10]). However, secondary analyses suggested these differences may have been caused in part by attrition bias.

None of the included RCTs was performed in the specific population for which nalmefene has been indicated, and none compared nalmefene with another medication such as naltrexone. A key conclusion of the SRMA is that more trials are needed. However, these findings call into question the regulatory approval of nalmefene for this purpose. The authors state, "Clinicians must be aware that the value of nalmefene for the treatment of alcohol addiction is not established. At best, nalmefene has limited efficacy in reducing <u>alcohol consumption</u>."

More information: Palpacuer C, Laviolle B, Boussageon R, Reymann JM, Bellissant E, Naudet F (2015) Risks and Benefits of Nalmefene in the Treatment of Adult Alcohol Dependence: A Systematic Literature Review and Meta-Analysis of Published and Unpublished Double-Blind Randomized Controlled Trials. *PLoS Med* 12(12): e1001924. DOI: 10.1371/journal.pmed.1001924

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