

# **A double-blind, placebo-controlled study of sertraline with naltrexone for alcohol dependence**

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## **Abstract**

### **Introduction**

Significant preclinical evidence exists for a synergistic interaction between the opioid and the serotonin systems in determining alcohol consumption. Naltrexone, an opiate receptor antagonist, is approved for the treatment of alcohol dependence. This double-blind placebo-controlled study examined whether the efficacy of naltrexone would be augmented by concurrent treatment with sertraline, a selective serotonin receptor uptake inhibitor (SSRI).

### **Methods**

One hundred and thirteen participants meeting DSM IV alcohol dependence criteria, who were abstinent from alcohol between 5 and 30 days, were randomly assigned to receive one of two treatments at two sites. One group received naltrexone 12.5 mg once daily for 3 days, 25 mg once daily for 4 days, and 50 mg once daily for the next 11 weeks, together with placebo sertraline. The other group received naltrexone as outlined and simultaneously received sertraline 50 mg once daily for 2 weeks, followed by 100 mg once daily for 10 weeks. Both groups received group relapse prevention psychotherapy on a weekly basis.

### **Results**

Compliance and attendance rates were comparable and high. The groups did not differ on the two primary outcomes, time to first drink and time to relapse to heavy drinking, or on secondary treatment outcomes. With the exception of sexual side effects which were more common in the combination group, most adverse events were similar for the two conditions.

## **Conclusions**

As the doses are tested in combination with specialized behavioral therapy, this study does not provide sufficient evidence for the combined use of sertraline and naltrexone above naltrexone alone.

**Keywords:** Alcohol dependence; Sertraline; Naltrexone; Clinical trial; Alcohol typology

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