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## **Effectiveness and safety of baclofen for maintenance of alcohol abstinence in alcohol-dependent patients with liver cirrhosis: randomised, double-blind controlled study**

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## Summary

### Background

Intervention to achieve alcohol abstinence represents the most effective treatment for alcohol-dependent patients with liver cirrhosis; however, anticraving drugs might worsen liver disease. We aimed to investigate the effectiveness and safety of baclofen in achieving and maintaining alcohol abstinence in patients with liver cirrhosis.

### Methods

Between October, 2003, and November, 2006, **148 alcohol-dependent patients with liver cirrhosis** were referred to the Institute of Internal Medicine, Rome, Italy. 84 were randomly allocated either oral baclofen or placebo for 12 weeks. Primary outcome was proportion of patients achieving and maintaining alcohol abstinence. Measures of this outcome were total alcohol abstinence and cumulative abstinence duration, which were assessed at outpatient visits. Relapse was defined as alcohol intake of more than four drinks per day or overall consumption of 14 or more drinks per week over a period of at least 4 weeks. Analysis was by intention to treat. This study is registered with [ClinicalTrials.gov](#), number [NCT00525252](#).

### Findings

Of 42 patients allocated baclofen, 30 (71%) achieved and maintained abstinence compared with 12 (29%) of 42 assigned placebo (odds ratio 6.3 [95% CI 2.4–16.1];  $p=0.0001$ ). The number of dropouts (termination of treatment) did not differ between the baclofen (6/42 [14%]) and placebo (13/42 [31%]) groups ( $p=0.12$ ). Cumulative abstinence duration was about twofold higher in patients allocated baclofen than in those assigned placebo (mean 62.8 [SE 5.4] vs 30.8 [5.5] days;  $p=0.001$ ). No hepatic side-effects were recorded.

### Interpretation

Baclofen is effective at promoting alcohol abstinence in alcohol-dependent patients with liver cirrhosis. The drug is well tolerated and could have an important role in treatment of these individuals.