

## A Randomised Clinical Trial of Baclofen for the Treatment of Alcohol Dependence

### Authors:

K C MORLEY<sup>1</sup>, A J BAILLIE<sup>2</sup>, G DORE<sup>3</sup>, N PHUNG<sup>4</sup>, I FRASER<sup>1</sup>, A FURNEAUX-BATE<sup>1</sup>, P HABER<sup>1,5</sup>

<sup>1</sup>NHMRC Centre of Research Excellence in Mental Health and Substance Use, The University of Sydney, Sydney, NSW, <sup>2</sup>NHMRC Centre of Research Excellence in Mental health and Substance Use, Macquarie University, Sydney, NSW, <sup>3</sup>Herbert St Alcohol Clinic, Royal North Shore Hospital, Sydney, NSW, <sup>4</sup>Centre for Addiction Medicine, Westmead Hospital, Sydney, NSW, <sup>5</sup>Drug Health Services, Royal Prince Alfred Hospital, Sydney Local Health District, Sydney, NSW

**Introduction and Aims:** Baclofen has been reported to be effective for alcohol dependence. However, the literature is inconclusive and this treatment remains controversial. We conducted a 12 week double-blind, placebo-controlled randomized clinical trial of baclofen in the treatment of alcohol dependence across three treatment centres in Australia.

**Design and Methods:** 104 alcohol-dependent patients were randomized to receive placebo, baclofen 30 mg/day or 75 mg/day. Outcome measures included time to lapse and relapse ( $\geq 5$  drinks for men and  $\geq 4$  for women, drinks per drinking day, number of heavy drinking days and percentage days abstinent).

**Results:** Intention-to-treat analyses revealed a significant effect of treatment on time to lapse ( $\chi^2 = 6.80$ ,  $p < 0.05$ ) with 30 mg/day baclofen delaying time to lapse compared to placebo ( $d = 0.45$ ,  $p < 0.05$ ). There was no significant effect of baclofen on time to relapse ( $p$ 's  $> 0.05$ ). A beneficial effect of baclofen relative to placebo was observed for percentage days abstinent ( $p < 0.05$ , placebo = 43%, baclofen 30 mg = 68%, baclofen 75 mg = 65%). In the 75 mg group, 23% withdrew from the study citing side-effects or as a result of a serious adverse event compared to 1% in the 30 mg group and 3% in placebo ( $\chi^2 = 6.17$ ,  $P < .05$ ).

**Discussion and Conclusions:** Low dose baclofen may delay the time to lapse and increase days abstinent. However, there were several adverse events suggesting the role for this medication may be limited to specialist services.