

Study suggests prescribing of baclofen for alcohol dependence 'should be reconsidered'

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The drug baclofen has received high visibility as a possible breakthrough treatment for alcohol dependence. Now a new randomised controlled trial from the University of Amsterdam found no evidence for the usefulness of high-dose baclofen in treating alcoholism when added to psychosocial treatments.

Recent trials have suggested high doses of the GABA-b agonist baclofen can be effective in the treatment of alcohol dependent patients. These studies, coupled with individual patient testimonies, have given baclofen a high public profile, prompting the French authorities in 2014 to give permission to physicians to prescribe high doses baclofen for alcohol-dependent patients, pending results from ongoing randomized clinical trials. Even before that permission, more than 200,000 persons had used baclofen "off label" in France alone. Baclofen is licenced for use as a skeletal muscle relaxant for spasms (spasticity).

Now, researchers from the Netherlands have carried out the largest [randomised controlled trial](#) (RCT) on baclofen for [alcohol dependence](#) so far. Their report, published in the peer-reviewed journal *European Neuropsychopharmacology* (December 2016), indicates that the effects of the drug may add little to the effect provided by psychosocial treatment.

151 alcoholic patients took part in the 16 week trial. 58 were given high-dose baclofen (starting with low dose, with the dose rising to up to 150 mg/day), low dose baclofen (31 patients, 30 mg/day), or placebo (62

patients). At the end of the trial the researchers found no differences in relapse rates (measured as the time to the first heavy drinking day post-treatment) between the groups: about 25% relapsed in each group.

Lead researcher, Professor Reinout Wiers (University of Amsterdam), said:

"This came as a surprise to us. In August 2015 a small German RCT had indicated that high dose baclofen showed good results, but their control group did not receive any treatment, whereas all our patients, including the placebo group, received psychosocial treatment. Together these studies indicate that baclofen may be as effective as psychosocial care, but does not seem to increase effectiveness further. This means that we may have to further study the effectiveness of baclofen before we can recommend it for use. For example, perhaps it can help a subgroup of alcohol-dependent patients who do not respond to psychosocial treatment. We believe that prescribing baclofen widely, as currently happens in France, might be premature and should be reconsidered".

Professor Wiers continued:

"We are planning a new RCT, where we will test high dose Baclofen, up to 330 mg per day, in alcohol-dependent patients who have not responded to regular psychological treatment. For comparison, the maximum recommended adult dose of baclofen for its normal (spasticity) use is 80 mg/day. We need to consider safety and side-effects. We are not closing the door on baclofen, but we are saying that we need more research".

Commenting, Professor Jonathan Chick, Medical Director, Castle Craig Hospital, Edinburgh, Scotland said:

"Baclofen showed promise in the original trials in Italian liver clinics

where patients did not receive intensive psychosocial treatment. The new Dutch study recruited [patients](#) from 4 and 6 week residential programmes, one of which was based on the 12-step model. Intensive [treatment](#), especially with 12-step aftercare, is known to be powerful as shown here – all groups had better outcomes than usual in European studies. Given that such good results are obtained with [psychosocial treatment](#), any additional effects of baclofen probably wouldn't reach statistical significance in a group of this size."

The use of Baclofen for alcohol dependence was stimulated by the book 'The end of my addiction', written by the French physician Olivier Ameisen, who claimed to have cured his own alcohol dependence by self-administering a [high dose](#) of Baclofen. Until then, Baclofen had been used in a much lower dose as a muscle relaxant for spasms (spasticity).

More information: Esther M. Beraha et al. Efficacy and safety of high-dose baclofen for the treatment of alcohol dependence: A multicentre, randomised, double-blind controlled trial, *European Neuropsychopharmacology* (2016). [DOI: 10.1016/j.euroneuro.2016.10.006](#)

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