

Weak evidence for prescribed alcohol drug, say scientists

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Credit: University of Stirling

A drug being used to treat alcohol problems in the UK was licensed for use despite insufficient evidence to prove its effectiveness, new research led by the University of Stirling has found.

The drug nalmefene, marketed as Selincro, was approved in Europe in February 2013 and was subsequently recommended by the UK National Institute for Health and Care Excellence (NICE).

Yet a team of scientists have found problems with the way clinical trials were conducted and analysed, making it impossible to know how much the drug actually helps to reduce drinking in patients dependent on

alcohol.

Outlined in the journal *Addiction*, a group of experts analysed the published studies of nalmefene that formed the basis for the licensing and NICE decision. They concluded that evidence of its effectiveness was weak, and any possible effect on patients was small at around a one drink per day reduction on average.

In the trials, side effects were generally more common in patients taking nalmefene, who were also more likely to drop out of the trials. The research also found nalmefene is more expensive than similar drugs on the market and that no comparison with these alternatives was made.

Dr Niamh Fitzgerald, a pharmacist and Lecturer in Alcohol Studies at the University's Institute for Social Marketing led the study. She said: "It's vitally important that we know that prescribed drugs are effective in treating the intended problem. In this case, we found problems with the registration, design, analysis and reporting of these [clinical trials](#) which did not prevent the drug being licensed or recommended for use.

"We believe this creates a difficulty for doctors trying to treat alcohol dependence and throws up critical questions for regulators around why a drug was licensed without a bank of high quality, reliable evidence."

The [drug](#) is currently licensed to be used in conjunction with psychosocial support to reduce alcohol consumption in patients diagnosed with [alcohol dependence](#), with consistently high [alcohol](#) consumption levels, but who do not experience physical withdrawal symptoms when they stop drinking.

Provided by University of Stirling

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