A PILOT RANDOMISED CONTROLLED TRIAL OF ORAL VARENICLINE VERSUS ORAL NALTREXONE FOR THE TREATMENT OF ALCOHOL DEPENDENCE

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Introduction and Aims: Varenicline (Champix®) is a partial α4β2 nicotinic acetylcholine receptor agonist approved for tobacco cessation. There are promising findings for alcohol dependence in trials with placebo controls but not yet with an active control group. Aim: To conduct a pilot study examining the feasibility of conducting a safety and efficacy RCT of varenicline (experimental condition) compared to oral naltrexone (active control) for the outpatient treatment of alcohol dependence.

Design and Methods: The study was a double-blinded, parallel-group randomised active-controlled trial over an 8-week medication period. Treatment-seeking alcohol-dependent patients were allocated into one of the two groups using a 1:1 random allocation: (1) varenicline (1 mg bd), (2) naltrexone 50mg/day (50 mg every morning + matched placebo nocte). The study was conducted at The Langton Centre.

Results: Half completed the protocol (3 of 5 varenicline, 2 of 5 naltrexone). Days abstinent increased from 0% to 80% amongst completers. Days of drinking and heavy drinking decreased over the trial for both conditions, with only one participant drinking on one day at follow up visit 2. Physical and mental health improved over the trial. Blinding was unsuccessful: 75% of varenicline and 50% of naltrexone participants guessed correctly.

Discussions and Conclusions: For those who remained in the trial, the number of days of drinking decreased. However, the high dropout rate and unsuccessful blinding should be addressed in any future studies investigating this medication.

Implications for Practice or Policy (optional): The results of this pilot study will inform the design and procedures to be used in future large scale efficacy studies.

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