

Double blind clinical trials for alcohol dependence

As the Australian community begins to recover from the effects of COVID-19, it is important that individuals are aware of all treatment options for alcohol use disorder including clinical trials that are currently recruiting potential participants. The addiction specialists and researchers at Royal North Shore Hospital Drug and Alcohol Service are conducting a study of topiramate versus naltrexone for alcohol use disorder in alignment with recommended CoVid safe practices to maintain patient safety. The main aims of the study are to evaluate the clinical effectiveness, tolerability and cost-effectiveness of topiramate compared to naltrexone. A genotyping sample is also obtained from patients to determine whether the GRIK1/OPRM1 allele moderates a patient's response to topiramate/naltrexone.

The treatment programme involves 3 months of free daily medication (either naltrexone 50mg or topiramate up to 200mg), weekly medical appointments with the addiction specialists, frequent blood tests to monitor liver function and the opportunity to participate in counselling. Follow up appointments are arranged with the treating clinician post-trial as a standard of care for all research patients. Through this trial we hope to create a more supportive environment for patients wishing to commence alcohol pharmacotherapy and encourage patients to either maintain abstinence or reduce their drinking.

Trial 1: Naltrexone and Topiramate

Most suitable for patients who need significant support in the community (weekly appointment attendance) and would like to commence an alcohol pharmacotherapy

Patients receive:

- 12 weeks medication (randomised to 200mg topiramate or 50mg naltrexone daily)
- Medical appointments, research appointments, medical management (brief medication adherence counselling)
- Optional counselling (free)

Inclusion Criteria:

- a) Alcohol dependence according to DSM-V criteria
- b) Willingness to provide written informed consent and blood sample for genotyping
- c) Age 18-70
- d) Average weekly alcohol consumption ≥ 25 stds for women and ≥ 30 stds for men

Exclusion Criteria:

- a) Active major psychological disorder associated with significant risk of suicide, psychosis or signs of impaired cognitive functioning (*flexible- clinician assessed*)
- b) Pregnancy or lactation
- c) Current use of any psychotropic medication other than antidepressants
- d) Opioid abuse, opioid dependence or on opioid maintenance treatment
- e) Use of antiretroviral dolutegravir
- f) Any other substance dependence other than nicotine
- g) Clinically significant liver disease (AST, ALT levels $> 3x$ upper normal limit)

- h) Recent history of nephrolithiasis
- i) History of glaucoma

For more information or to refer a patient please call Ms Claire Adams or text 0474 110 954.
Patients can also self-refer using the same number or email sydneyalcoholtreatmentgroup@gmail.com