

Cannabis Medicine Clinical Trial for Chemotherapy-Induced Nausea and Vomiting



This is the largest, most definitive clinical trial ever undertaken to evaluate the potential of a cannabis medicine to prevent nausea and vomiting in chemotherapy patients.

It plays a critical role in understanding how cannabis medicines may provide relief to chemotherapy patients who have not had their symptoms controlled by standard treatments.

Clinical Associate Professor Peter Grimison, a medical oncologist from Chris O'Brien Lifehouse and the University of Sydney, leads the research team of cancer, addiction and clinical toxicology specialists, including experts from Royal Prince Alfred Hospital and leading cancer centres in NSW.

The trial is part of a \$9 million commitment by the NSW Government towards clinical trials evaluating the safety and efficacy of cannabis medicines in treating symptoms and conditions. A further \$12 million has been invested in the NSW Centre for Medicinal Cannabis Research and Innovation.

About the trial

The first stage has enrolled 81 patients at Chris O'Brien Lifehouse and 10 other leading NSW cancer centres. The treatment has been assessed to be safe and effective. A second stage double-blind randomised controlled trial has now opened and will enrol a further 170 patients.

The trial is using an oral, plant-derived, pharmaceutical-grade capsule containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

The trial is measuring participants' relief from symptoms and any side effects. The trial is being conducted in accordance with the standard ethical process for clinical trials and has received regulatory approval. It has been reviewed and approved by an appropriate Human Research Ethics Committee.

Participating in the trial

Around one-third of patients receiving potent intravenous chemotherapy still experience vomiting and around half still experience nausea, despite being given the best standard therapies for symptom relief. These patients may be eligible for this trial.

Participants must be over 18, undergoing intravenous chemotherapy for cancer and have significant symptoms during treatment despite being given the best standard of care.

After enrolment, participants begin taking the trial cannabis medicine or placebo the day before they commence their first chemotherapy cycle, and continue taking it for five days after that cycle. They remain on the study treatment for three consecutive cycles of chemotherapy and return to the clinic 30 days after the last dose for a follow-up visit.

For information on the enrolment process, contact your oncologist to discuss the eligibility criteria.

The trial design allows a patient continued access to the cannabis medicine, free of charge, if it has proven beneficial during the trial. First, a statistician reviews the patient data to determine if the patient was receiving the cannabis medicine or the placebo. If the patient was receiving the cannabis medicine and it was effective, they will be supplied sufficient doses for all subsequent cycles of that chemotherapy treatment.

Further information

To find out more about these trials:

- email the Centre for Medicinal Cannabis Research and Innovation MOH-CannabisTrial@health.nsw.gov.au
- write to Centre for Medicinal Cannabis Research and Innovation, Locked Bag 2030, St Leonards, NSW 1590

For more information about cancer services in NSW, visit the Cancer Institute NSW website:

www.cancerinstitute.org.au