

# NSW CLINICAL TRIAL FOR PATIENTS WITH CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING



Health

## This NSW Government-funded trial is the world's largest and most definitive clinical trial ever of cannabis-derived medicine for the prevention of nausea and vomiting from chemotherapy.

It will play a critical role in developing a better understanding of how cannabis products may provide relief to patients undergoing chemotherapy who have not had their symptoms controlled by standard treatments.

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

This trial forms part of the NSW Government's \$9 million investment in clinical trials for cannabis products. A further \$12 million is being invested in the NSW Centre for Medicinal Cannabis Research and Innovation.

## About the trial

The first stage of the trial is expected to enrol 80 patients at Chris O'Brien Lifehouse and other leading cancer centres in NSW. If the data from this pilot trial shows the medicine works and is well tolerated, it will be followed by a double-blinded randomised controlled trial expected to enrol 250 patients.

The research will be using an oral, plant-derived, pharmaceutical-grade capsule containing 2.5mg each of delta-9-Tetrahydrocannabinol (THC) and Cannabidiol (CBD) developed and supplied by Canadian medicinal cannabis company Tilray.

The trial will measure participants' symptoms, their relief from symptoms and any side effects. It will be conducted in accordance with the standard ethical process for clinical trials and is subject to regulatory approval. It has been reviewed and approved by an appropriate Human Research Ethics Committee.

## Participating in the trial

Many people who undergo chemotherapy respond well to standard therapies to prevent any symptoms of nausea and vomiting that may accompany this important cancer treatment. However, about one-third of people do not gain complete symptom relief from these therapies.

People who continue to have significant symptoms during chemotherapy despite being given best standard care may be invited to join the trial.

Participants will be over 18 years of age, be undergoing chemotherapy for cancer and have significant symptoms during chemotherapy despite being given the best standard of care.

Participants will visit the study clinic over a period of about three months. Patients will begin taking the study drug the day before they start chemotherapy, and continue taking it for four days after chemotherapy.

Participants will be on the study treatment for three consecutive cycles of chemotherapy treatment (between six and nine weeks). After completing three cycles of chemotherapy, patients will be asked to return to the clinic 30 days after the last dose for a follow-up visit.

The trial has strict eligibility criteria. Patients will be screened before being admitted to the trial to ensure that it is safe and appropriate for them to participate.

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

For more general information on the trials:

- call the Cannabis Trials Help Line on **1800 217 257**
- write to **Cannabis Trials, NSW Ministry of Health, Locked Mail Bag 961, North Sydney, NSW 2059**
- email the NSW Ministry of Health **[cannabistrial@doh.health.nsw.gov.au](mailto:cannabistrial@doh.health.nsw.gov.au)**

For more information about cancer services in NSW visit the Cancer Institute NSW website **[www.cancerinstitute.org.au](http://www.cancerinstitute.org.au)**