Cannabis Medicine Clinical Trial for Chemotherapy-Induced Nausea and Vomiting

This NSW Government-funded trial is the largest, most definitive clinical trial ever undertaken to evaluate the use of a cannabis medicine to prevent nausea and vomiting from chemotherapy.

This trial is part of the NSW Government's $21 million commitment to develop a better understanding of how cannabis medicines may provide relief to patients undergoing moderately or highly emetogenic intravenous chemotherapy treatment.

Trial rationale

Previous trials of the antiemetic effects of cannabis medicines have compared cannabis medicines to outdated antiemetic regimens or have been too small to definitively influence clinical practice.

This trial program aims to accurately evaluate the efficacy of a specific cannabis medicine in alleviating both vomiting and nausea in those whose symptoms are poorly controlled with best standard antiemetic regimens.

Trial design

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

The first stage of the study, to examine the safety and efficacy of the product, has enrolled 81 patients at Chris O'Brien Lifehouse and 10 other leading NSW cancer centres. This double-blind randomised controlled trial compared the best standard supportive care (a 5-HT3 receptor antagonist and placebo, together with dexamethasone, and, for most regimens, an NK-1 antagonist) against a pharmaceutical-grade oil-in capsule containing a fixed ratio of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), while the patients receive best standard care.

The treatment has been assessed to be safe and effective, and a second stage double-blind randomised controlled trial has now opened and will enrol a further 170 patients. This trial will gather information about the effectiveness, adverse events, acceptability and resource use of such a regime.

It is important to note that, similar to other trials of antiemetogenic agents, the intervention will only be tested for up to three cycles of chemotherapy (up to nine weeks).

Participating in the trial

To be eligible, patients will be aged over 18 years with known malignancy of any stage, receiving moderate to highly emetogenic intravenous chemotherapy, requiring more than one further cycle of chemotherapy and experiencing significant chemotherapy-induced nausea and vomiting during cycle one. The trial complies with requirements regarding Therapeutics Goods registration, international import and export permits and Ethics Committee approval.

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 the trial and trial sites, please see:
https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=370473&isReview=true