MEDICINAL CANNABIS NSW CLINICAL TRIAL FOR PATIENTS WITH TERMINAL CANCER

NSW GOVERNMENT Health

This trial is part of the NSW Government's commitment to develop a better understanding of how cannabis products may provide relief to adult cancer patients in the final stages of life.

This is the first time in Australia that vaporised cannabis flower bud will be used in a clinical trial to determine its ability to improve appetite and appetite-related symptoms for terminally ill patients.

The trial is led by UNSW Professor Meera Agar in collaboration with researchers from several universities.

Rationale for the trial

The trial aims to determine whether medicinal cannabis can improve appetite and appetite-related symptoms in an advanced cancer palliative care population.

The potential of cannabinoids to alleviate other distressing symptoms in terminally ill patients is also unclear. These symptoms include fatigue, low mood, weight loss, nausea, insomnia and pain.

This trial will help answer important questions about safety, efficacy, dosage and frequency, side effects and what the best delivery mode for the medicinal cannabis might be.

Trial design

The trial will be undertaken in two parts:

1. Phase I/II, dose ranging study of the pharmacokinetics, dose-response parameters, and feasibility of vaporised cannabis flower bud.
2. Phase III double-blind randomised controlled trial.

The Phase II pharmacokinetic study of a cannabis product (Bedrobinol® 13.5% THC) will enrol about 30 patients. This study will inform feasibility, tolerability and the dosing regimen. It will be conducted at Calvary Mater Newcastle hospital and St Vincent's Sacred Heart Health Service, Darlinghurst, under the supervision of a clinical pharmacologist and the trial investigator.

The Phase III double-blind RCT will be informed by the results of Phase II. Depending on the results of the initial stage of the trial, the second part may then enrol up to 250 more patients at several metropolitan and regional hospitals in NSW in a double-blind randomised controlled trial.

This trial will explore more definitively the effect on appetite and related symptoms, and safety profile. It will also explore quality of life, impact on other cancer-related symptoms and cost effectiveness.

Participating in the trial

Only patients with advanced cancer who are over 18 years of age and who meet specific additional criteria can be considered for enrolment.

Participants will have blood samples taken at multiple time points up to four hours following each morning dose to determine the concentration of the drug in the blood. They will also be asked to complete questionnaires and a daily food record to monitor the effect on appetite, mood and other factors.

Patients will be screened before being admitted to the trial. It will be conducted in accordance with the standard ethical process for clinical trials.

For more general information on the trials:

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

Additional information about the trial and trial sites is available at:

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=369767&isReview=true