

# MEDICINAL CANNABIS NSW CLINICAL TRIAL FOR PATIENTS WITH TERMINAL CANCER



Health

**This is the first time in Australia that vaporised cannabis flower bud will be used in a clinical trial. The aim is to develop a better understanding of how it may provide relief to adult cancer patients in the final stages of life.**

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 through the NSW Centre for Medicinal Cannabis Research and Innovation.

## About the trial

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

It aims to determine whether medicinal cannabis can improve appetite and appetite-related symptoms in advanced cancer palliative care patients.

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.

The cannabis flower bud used in the first stage of the trial has been produced by Bedrocan BV®, a medicinal cannabis company in The Netherlands.

## Part one

The first part of the trial will enrol about 30 patients in order to answer the following questions:

- Can a potential cannabis product be successfully given to patients by inhaling it as a vapour?
- Is the potential cannabis product well tolerated by patients, that is, does it cause any unwanted side effects?
- What is the ideal dose of the potential cannabis product and how often should it be given?

## Part two

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

## 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. Enrolment of patients for the first stage of the trial will take place at St Vincent's Sacred Heart Health Service and Calvary Mater Newcastle hospital.

Participants will be administered varying doses of vaporised cannabis flower bud (Bedrobinol® 13.5% THC) one hour before meals three times a day for a period of seven days, unless side effects occur.

Participants will have blood samples taken at multiple time points 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.

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.

It will be conducted in accordance with the standard ethical process for clinical trials.

**For information on the process for enrolment, please contact your treating oncologist or palliative care specialist.**

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)