

Information for health professionals

CARE NSW

Cannabinoids for symptom control in advanced cancer, an open label prospective clinical trial in NSW

Introduction

The CARE NSW Trial is a non-randomised, open-label, Phase IV real-world clinical trial that includes Phase II pharmacokinetic sampling. The trial is a preliminary study to describe the changes in a participant's quality of life, clinical benefit, toxicity, tolerability and costs of a selection of cannabis medicine products available in NSW.

The aim

It is hoped the information collected in the study will guide the use of cannabis medicines to control symptoms in people with advanced cancer. The aims of the study are to:

1. profile how advanced cancer patients use cannabis medicines in a real-world setting via the collection of prospective data on the open-label product, dose, efficacy, safety, pharmacokinetics and pharmacodynamics
2. provide preliminary safety, tolerability and efficacy evidence to guide future studies

Who is eligible?

Patients with:

- advanced cancer with or without stable disease; and
- predicted life expectancy of 3 to 12 months; and
- persistent symptoms of anorexia, nausea or refractory pain, not responsive to standard practice.

Prior access to authorised cannabis medicines or current use of illicit cannabis is not an exclusion.

Full eligibility criteria are available on the ANZCTR website. Search under: **ACTRN12619000265178**

Treatment

Patients will be prescribed either a predominately THC product or a 1:1 THC:CBD product from a defined selection based on their index symptom(s).

All cannabis medicines are oral oils, currently available in Australia that meet regulatory

requirements for prescribed cannabis medicines, including TGO 93 guidelines.

Treatment will be given in addition to the usual medical treatments for advanced cancer and symptoms, including other medicines and radiotherapy.

Follow-up

Patients will remain enrolled in the trial and followed-up at 1-2 weeks, 6 weeks, 3 months, 6 months and every 3 months thereafter until such a time that the participant is no longer able to take the product due to withdrawal or death.

Contact

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The day-to-day management of the Trial is managed by the NHMRC-funded Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE).

Chief Principal Investigator is Professor Jenny Martin

More information

To find out more about this trial:

- 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=376790&isReview=true>