A Phase II Study of Medicinal Cannabis Products in the Treatment of Chronic Pain in Patients with Opioid Dependence: a Study Protocol

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Background:

Chronic low back pain is commonly associated with opioid dependence, with many patients reporting limited benefit from opioids and poor access to effective non-pharmacological treatments. Medicinal cannabis (MC) products containing tetrahydrocannabinol (THC) and cannabidiol (CBD) are increasingly prescribed in Australia for pain management; however, evidence regarding their effectiveness in people with chronic pain and opioid dependence remains limited. This Phase II study will examine the effects of THC-only, CBD-only and THC-CBD combination products compared with placebo in adults with chronic low back pain and prescription opioid dependence.

Method/ Design:

This is a Phase II double-blind, randomised within-subject crossover study involving four medication phases: (A) placebo; (B) THC-only (20 mg daily); (C) THC-CBD (20 mg/400 mg daily); and (D) CBD-only (400 mg daily). Each phase includes 14 days of study medication followed by a 7-day washout period, resulting in a total 12-week trial duration. Outcomes will be assessed during days 8–14 of each medication phase using Ecological Momentary Assessment (EMA) and conventional outcome measures. Twenty-four adults aged 18–75 years with chronic low back pain (pain severity ≥4/10) and dependence on prescribed opioid medication will be recruited from two sites across NSW, Australia.

Research Hypothesis:

Oral THC, CBD and THC-CBD combination products will significantly reduce pain severity by ≥1 point on a 0–10 pain intensity scale relative to placebo.

Discussion:

This study will contribute important feasibility, safety and preliminary efficacy data regarding cannabinoid formulations in people with chronic pain and opioid dependence. Findings will help inform future Phase III trials, optimise methodologies including EMA in pain and substance use research, and contribute to clinical practice and policy discussions regarding evidence-based medicinal cannabis prescribing.

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