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Oral THC:CBD cannabis extract for refractory chemotherapy-induced nausea and vomiting: a randomised, placebo-controlled, phase II crossover trial

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Abstract

Background: This multicentre, randomised, double-blinded, placebo-controlled, phase II/III trial aimed to evaluate an oral THC:CBD (tetrahydrocannabinol:cannabidiol) cannabis extract for prevention of refractory chemotherapy-induced nausea and vomiting (CINV). Here we report the phase II component results.

Patients and methods: Eligible patients experienced CINV during moderate-to-high emetogenic intravenous chemotherapy despite guideline-consistent antiemetic prophylaxis. Study treatment consisted of one cycle of 1-4 self-titrated capsules of oral THC 2.5 mg/CBD 2.5 mg (TN-TC11M) three times daily, from days -1 to 5, and 1 cycle of matching placebo in a crossover design, then blinded patient preference for a third cycle. The primary end point was the proportion of participants with complete response during 0-120 h from chemotherapy. A total of 80 participants provided 80% power to detect a 20% absolute improvement with a two-sided P value of 0.1.

Results: A total of 81 participants were randomised; 72 completing two cycles were included in the efficacy analyses and 78 not withdrawing consent were included in safety analyses. Median age was 55 years (range 29-80 years); 78% were female. Complete response was improved with THC:CBD from 14% to 25% (relative risk 1.77, 90% confidence interval 1.12-2.79, P = 0.041), with similar effects on absence of emesis, use of rescue medications, absence of significant nausea, and summary scores for the Functional Living Index-Emesis (FLIE). Thirty-one percent experienced moderate or severe cannabinoid-related adverse events such as sedation, dizziness, or disorientation, but 83% of participants preferred cannabis to placebo. No serious adverse events were attributed to THC:CBD.

Conclusion: The addition of oral THC:CBD to standard antiemetics was associated with less nausea and vomiting but additional side-effects. Most participants preferred THC:CBD to placebo. Based on these promising results, we plan to recruit an additional 170 participants to complete accrual for the definitive, phase III, parallel group analysis.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12616001036404; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=370473&isReview=true.

Keywords: antiemetic; cannabidiol; cannabis; chemotherapy-induced nausea and vomiting; randomised trial.

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