

CannabisCINV - Medicinal cannabis to prevent chemotherapy-induced nausea and vomiting (CINV): Results of the pilot phase of the study.

What is the trial about?

Nausea and vomiting are common side effects of chemotherapy. A number of medicines are used to prevent these two side effects (prophylaxis), often several together, but these two symptoms remain among the most distressing and feared consequences of chemotherapy.

What is the aim of the trial?

This trial aims to find out if medicinal cannabis helps patients taking chemotherapy who suffer from nausea and/or vomiting despite using recommended nausea medications.

What treatment is being studied?

The medicinal cannabis product is a capsule that contains both tetra-hydrocannabinol (THC) and cannabidiol (CBD) which have been extracted from cannabis plants. The capsules are taken by mouth three times a day for six days during one cycle of chemotherapy.

Who participated in the study?

This study allowed adults aged 18 years and over with any cancer type who were being treated with chemotherapy that was likely to cause nausea and vomiting. To be included in the study, patients must have already experienced nausea and vomiting (during chemotherapy) despite taking nausea prevention medications that are known to be effective. Patients must also have at least two more treatments with the same chemotherapy agents planned.

How was the study done?

The study is being performed in two parts, a smaller pilot phase (Part 1), which has just been completed and was done to tell us whether or not to move into the larger phase (Part 2). Here we report the results of Part 1 of the study.

Part 1 of the trial has finished. Eighty-one people took part, and were allocated by chance (randomised) to receive medicinal cannabis or identical placebo capsules for one cycle of treatment and then swapped treatment for the next cycle of treatment, without them or their doctors knowing which they had received, the cannabis or the placebo. (This is called a double-blind trial).

The participants in the study were asked to keep a diary and recorded whether they had nausea, how bad their nausea was, whether they needed to take extra nausea medicines and whether they vomited in the first 5 days of their chemotherapy treatment cycle. The main study outcome was the proportion of people who had no vomiting and did not need to take

extra nausea medicines. At the end of the study, the participants were asked which cycle they preferred, (cycle 1 or cycle 2), without knowing when they had taken medicinal cannabis.

What were the effects of the treatment?

Nausea and vomiting were improved with the addition of medicinal cannabis, with 25% of patients having no vomiting and not needing extra nausea medicines when taking medicinal cannabis, compared to 14% when taking placebo. There were similar improvements seen with nausea severity, and the majority of people said they preferred the treatment that included medicinal cannabis.

What were the side-effects of the treatment?

Expected side-effects of medicinal cannabis such as sedation, dizziness and drowsiness were rated as moderate to severe in about one third of participants. There were no serious or life-threatening side effects caused by the medicinal cannabis.

What does this mean for trial patients?

Participants in this study showed an improvement in the nausea and vomiting caused by chemotherapy, but also had more side effects. The participants in this trial preferred medicinal cannabis to placebo.

How will the results help patients and doctors in the future?

These results are a promising sign that the addition of medicinal cannabis to traditional anti-nausea medication will assist in preventing the nausea and vomiting caused by chemotherapy, and that the extra side effects of medicinal cannabis are manageable.

What are the researchers going to do next?

The larger phase of the trial, which is ongoing, and will recruit an extra 170 people. This will help us to work out with much more certainty how effective medicinal cannabis is and whether it should be considered for use in routine cancer care.

Where can I find out more about the trial?

<https://ctc.usyd.edu.au/our-work/research-divisions/cancer/cancer-divisions/other-research/open-trials/cannabiscinv/>

<https://www.ncbi.nlm.nih.gov/pubmed/30209152>

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=370473>

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