

presentations. Diagnosis of advanced pancreatic cancer is associated earlier opioid commencement. People with pancreatic cancer may benefit from routine early referral to palliative care services to coordinate complex pain management needs due to earlier pain presentations and shorter prognosis.

OP-8

A FEASIBILITY RANDOMIZED CONTROLLED TRIAL COMPARING OPIOID DOSE ESCALATION VS. METHADONE ADDITION FOR REFRACTORY CANCER PAIN

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Background Cancer pain affects 38–85% of cancer patients, with higher incidence in advanced stages.¹ Poorly controlled cancer pain, often with neuropathic elements, presents a significant unmet medical need. Despite various opioid formulations, 47% of physicians report difficulties in managing opioid-refractory pain.² Methadone has shown superior efficacy to other opioids, such as morphine, especially for neuropathic pain poorly controlled by other opioids.³ Currently, opioid escalation is the standard, but is often inadequate, and although the methadone add-on (AO) method has been reported to be safe and effective for refractory cancer pain, no randomized controlled trials (RCTs) have been conducted.

Aims This study aims to explore the feasibility of conducting a double-blind RCT to assess the efficacy and safety of the methadone AO method for opioid escalation in patients with cancer pain.

Methods This study is a single-facility, double-blind, parallel-arm RCT. A total of 22 patients will be enrolled between July 2024 and September 2025. Eligible participants are adults with unresectable advanced cancer experiencing refractory cancer pain on an appropriate dose of opioid analgesia (60–300 mg oral morphine equivalent daily dose, OMEDD) and a Karnofsky Performance Status (KPS) >50. Participants will be randomized (1:1) to the methadone AO arm or the standard treatment arm. Evaluations will be conducted at baseline (randomization), day 1, 8, and 15. In the methadone AO arm, patients will receive over-capsulated methadone 5 mg or 10 mg, and in the 5 mg group, placebo will be used to unify the twice-daily dosing of the study drug. In the standard treatment arm, patients will receive over-capsulated oxycodone 10 mg or 20 mg. The primary endpoint is the completion rate of the two-week study treatment, defined as 70% or more. Secondary endpoints include changes in BPI scores before and after the study treatment and adverse events.

Discussion Several considerations influenced the study design. First, the methadone dosage required careful determination.

Previous studies suggest equivalence ratios of OMEDD 30–90 = 4:1, 90–300 = 6:1, and over 300 = 8:1. For this study, we set the morphine-to-methadone ratio at 6:1, which is safer than the 3:1 and 5:1 reported in other studies but less conservative than NCCN recommended 10:1. Second, the primary endpoint was defined as achieving a study completion rate of at least 70%. Although no prospective clinical trials exist, a Canadian cohort study (N=146) reported a continuation rate of 78.1% at Day 15 with a mean methadone dose of 6 mg. This data and discussions within our study group, led us to set a 70% completion rate. Finally, we chose a 2-week study period based on previous research: Mercadante et al. (n=108) found stable methadone doses over 4 weeks, and Bruera et al. (n=103) reported over 20% pain relief by Day 8 with no dose change between Days 14 and 28. Thus, 2 weeks is sufficient for efficacy and safety assessment. Based on the results of our study, we plan to conduct a larger-scale RCT of the methadone to establish a treatment for refractory cancer pain.

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OP-9

SHOULD WE GIVE UP ON LIDOCAINE TRIALS? IMPLICATIONS OF PRELIMINARY RESULTS OF THE LIDOCAINE FOR NEUROPATHIC CANCER PAIN FEASIBILITY STUDY (LICPAIN)

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Background Lidocaine infusions are used variably around Australia to treat people with neuropathic cancer pain. The LICPAIN trial aimed to determine the feasibility of conducting a double-blind randomised controlled trial of continuous subcutaneous lidocaine for neuropathic cancer pain. The primary objective was

Methods Palliative care inpatients at 5 metropolitan NSW sites were randomised to a 72-hour continuous infusion of subcutaneous lidocaine or placebo at 1–2mg/kg/hr, capped at 120mg/