

A Randomised, Double-Blind, Placebo Controlled, Multi-Site Study of Subcutaneous Ketamine in the Management of Cancer Pain

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Objectives

Ketamine is used commonly as an adjunct to opioids in the management of pain. The evidence to support this practice is limited. The aim of this study was to evaluate the role of subcutaneous ketamine in cancer pain.

Methods

Patients with pain related to malignant disease or its treatment, rated as $\geq 3/10$ despite adequate co-analgesia, were eligible if there has been no change in baseline opioid dose within the previous 48 hours. Participants were randomised to either ketamine or placebo, delivered subcutaneously at a dose titrated from 100 to 500mg/24hours, according to response and toxicity. Response was defined as a ≥ 2 point reduction in average Brief Pain Inventory (BPI) pain score from baseline with ≤ 4 breakthrough doses of analgesia. The primary endpoint was average pain score at start day 6. Secondary endpoints included adverse events, response at days 2-5 and quality of life. Ketamine would be considered superior to placebo if the response rate at start day 6 was 25% greater than that of placebo (assuming a placebo response rate of 30%).

Results

One hundred and eighty five participants were randomised from March 2008 to February 2011 to complete the planned sample size of 150. Primary analysis has confirmed the high placebo response rate ($25/92 = 27\%$) with no difference between active and placebo arms ($p = 0.55$).

Conclusion

This adequately powered, randomized controlled trial demonstrates the power of placebo and does not support the role of subcutaneous ketamine in the treatment of cancer pain in advanced cancer.