Author's response to reviews

Title: A randomised controlled trial comparing the efficacy of intranasal ketamine and fentanyl in the relief of moderate to severe pain in children with limb injuries: The PICHFORK Trial (Pain In CHildren Fentanyl OR Ketamine)

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Author's response to reviews: see over
To the Editors of Trials,

Please find our responses to the Editorial and Reviewer requests for manuscript ID;

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“The PICHFORK (Pain In CHildren Fentanyl OR Ketamine) trial comparing the efficacy of intranasal ketamine and fentanyl in the relief of moderate to severe pain in children with limb injuries: study protocol for a randomised controlled trial”

Kind regards,

Andis Graudins

1. Editorial request to modify title to conform to journal style; ________________:
study protocol for a randomised controlled trial.

RESPONSE: Title was changed to;

“The PICHFORK (Pain In CHildren Fentanyl OR Ketamine) trial comparing the efficacy of intranasal ketamine and fentanyl in the relief of moderate to severe pain in children with limb injuries: study protocol for a randomised controlled trial”

2. Responses to Reviewer’s report

a. Method of rescue analgesia to use would depend on treating doctor’s preference – IN fentanyl vs IV morphine? Would they start an IV line to administer rescue analgesia? Is this standard of care in Australia.

Redosing of intranasal analgesia with IN fentanyl is preferable in most paediatric cases with moderate to severe pain. However, in severe pain that has not responded to IN analgesia, it is up to the treating physician’s discretion to decide whether further analgesia will be administered intranasally as fentanyl or intravenously as morphine, particularly in cases where an IV is needed for other purposes. This is a clinical decision and accepted practice in Australia.
b. Does the use of rescue analgesic exclude the patient from the study?

RESPONSE: Line 160-161. “If rescue analgesia is needed, participation in the study will be terminated at that time.” The following sentence was added immediately after;

“Data collected to time of termination will be retained and included in the statistical analyses”

c. How will patients be monitored after IN Fentanyl or IN Ketamine? If a minor procedure needs to be done, (suturing or close reduction or splint application) would that be done after the study is completed (60 min after drug application)? If procedures are undertaken within the study period, the pain scores could be affected by the ‘procedural pain’.

RESPONSE: The study is assessing the response of patients to initial analgesia. This is not procedural sedation. Any patients requiring an emergent procedure on their limb injury (such as: significant limb deformity with vascular injury) will require time critical procedural sedation and by definition will be not be suitable for this study. In most cases, limb injuries are not in this severe category, and initial analgesia is required to facilitate pain free imaging studies and initial treatment.

d. Lines165-166. You mention VAS scores. I believe this also includes the FPS-R. I would prefer to say that the outcome will be reduction in PAIN SEVERITY SCORES.

RESPONSE: the lines were modified to read;

The primary outcome measure will be median reduction in pain severity scores 30 minutes (T30) after study medication administration.