

Investigation of the Potentiation of the Analgesic Effects of Fentanyl by Ketamine in Humans: a Double-blinded, Randomised, Placebo Controlled, Crossover Study of Experimental Pain

Submission date 10/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Adam Tucker

Contact details
Dept Anaesthesia
Monash Medical Centre
246 Clayton Road
Clayton
Australia
3168
+61 3 95946666
adam.tucker@med.monash.edu.au

Additional identifiers

Protocol serial number
MMC

Study information

Scientific Title

Investigation of the Potentiation of the Analgesic Effects of Fentanyl by Ketamine in Humans: a Double-blinded, Randomised, Placebo Controlled, Crossover Study of Experimental Pain

Study objectives

The current investigation explored the interaction between ketamine and the opioid fentanyl in the anticipation that a low dose of ketamine might potentiate the analgesic effect of fentanyl. Furthermore, it was hypothesised that the interaction of these drugs might be associated with selective potentiation of analgesia without associated increased sedation; that is that potentiation might occur in the context of a very low dose of ketamine that was not otherwise associated with brain effects such as sedation. It was hoped that the identification of such doses of ketamine may enable better future management of both opioid sensitive physiological pain and NMDA receptor-mediated sensitisation without the disadvantage of increased sedation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Pain

Interventions

The ten volunteers each attended five three-hour laboratory sessions on separate occasions. In each session, the volunteer received one of the following treatments:

Placebo (saline)

Propofol

Ketamine

Fentanyl

Ketamine and Fentanyl

Therefore, each volunteer was exposed to each of the five treatments, over five sessions, with the order of treatment randomised for each volunteer. During each session, the test battery was performed prior to drug administration as a measure of baseline and then repeated when the target concentrations were reached.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

ketamine, propofol, fentanyl

Primary outcome(s)

Pain threshold to electrical current, pain threshold to contact heat, pain threshold to pressure, visual analogue scale for sedation, Observer Assessment of Alertness/Sedation Scale (OASS), Symbol Digit Modalities Test (SDMT), auditory reaction time

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

Ten healthy male volunteers were recruited via bulletin board advertisements. The volunteers were trained in the test procedures employed and medically screened.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

10

Key exclusion criteria

Volunteers were excluded if they had a history of cardiac, neurological, or musculoskeletal disease. Other exclusion criteria included a history of drug abuse, pain syndromes, myasthenia gravis, acute narrow angle glaucoma, asthma, or heart failure, concurrent use of any analgesics, sedatives, erythromycin, monoamine oxidase (MAO) inhibitors, or allergy to propofol, fentanyl, or ketamine.

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Australia

Study participating centre

Dept Anaesthesia

Clayton

Australia

3168

Sponsor information

Organisation

Monash Medical Centre (Australia)

ROR

<https://ror.org/036s9kg65>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Monash Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/04/2005		Yes	No